SERIOUS HAZARDS OF TRANSFUSION SHOT

Annual Report 2010

Affiliated to the Royal College of Pathologists

The Steering Group comprises members representing the following professional bodies

British Blood Transfusion Society
British Society for Haematology
Faculty of Public Health Medicine
Institute of Biomedical Science
NHS Confederation
Health Protection Agency Centre for Infections
Royal College of Anaesthetists
Royal College of Nursing
Royal College of Obstetricians and Gynaecologists
Royal College of Paediatrics and Child Health
Royal College of Physicians
Royal College of Surgeons
The four UK Blood Services

Serious Hazards of Transfusion (SHOT)

Steering Group Chair	Dr Hannah Cohen
Interim Medical Director	Dr Sue Knowles
Operations Manager	Ms Alison Watt
Research Analyst	Mrs Hilary Jones until 31st March 2011 Ms Debbi Poles from 1st April 2011
Transfusion Liaison Practitioner	Mr Tony Davies
Clinical Incidents Specialist	Mrs Julie Ball
Laboratory Incidents Specialist	Mrs Hema Mistry
SHOT National Coordinator for Infectious Hazards (Health Protection Agency)	Ms Claire Reynolds

Working Expert Group (WEG) & Writing Group, on behalf of the SHOT Steering Group

Chair: Dr Sue Knowles

Dr Hannah Cohen, Ms Alison Watt, Ms Debbi Poles, Mrs Hilary Jones, Mr Tony Davies, Mrs Hema Mistry, Mrs Julie Ball, Mrs Debbie Asher, Mrs Claire Reynolds, Dr Catherine Chapman, Mrs Alexandra Gray, Mrs Joan Jones, Ms Clare Milkins, Dr Helen New, Dr Derek Norfolk, Dr Fiona Regan, Dr Hazel Tinegate

Steering Group (SG)

Chair: Dr Hannah Cohen

Name	**Representing**
Dr John Barbara	Founder Member
Prof Mark Bellamy	The Intensive Care Society
Dr Su Brailsford	Health Protection Agency
Mr William Chaffe	Institute of Biomedical Science
Dr Heidi Doughty	Defence Medical Services
Dr Roger Eglin	Transfusion Microbiology Specialist, NHSBT
Prof Adrian Evans	College of Emergency Medicine
Mr John Getty	Royal College of Surgeons
Dr Brenda Gibson	Royal College of Paediatrics and Child Health
Dr Patricia Hewitt	Consultant Specialist in Transfusion Microbiology, NHSBT
Ms Joanne Hoyle	Royal College of Nursing
Ms Mervi Jokinen	Royal College of Midwives
Ms Joan Jones	Institute of Biomedical Science; Clinical Advisory Group, Wales
Dr Sue Knowles	Interim Medical Director of SHOT
Prof John S P Lumley	Founder Member
Dr Sheila MacLennan	UK Forum
Mr John Marriott	Lay Member
Dr Brian McClelland	Founder Member
Dr Kieran Morris	Royal College of Pathologists; Northern Ireland Regional Transfusion Committee
Dr Andrew Mortimer	Royal College of Anaesthetists
Dr Tim Nokes	British Society for Haematology
Dr Derek Norfolk	British Committee for Standards in Haematology, CMO's National Blood Transfusion Committee
Dr Jonathan Potter	Royal College of Physicians
Dr Daghni Rajasingam	Royal College of Obstetricians and Gynaecologists
Dr Sam Rawlinson	Scottish Clinical Transfusion Advisory Committee
Ms Claire Reynolds	SHOT National Coordinator for Infectious Hazards; Health Protection Agency
Dr Dorothy Stainsby	Past National Medical Coordinator of SHOT
Dr Andrew Thillainayagam	British Society of Gastroenterology
Dr Dafydd Thomas	British Blood Transfusion Society
Dr Lorna Williamson	Founder Member

NB All members of the WEG are members of the Steering Group in their own right

Requests for further information should be addressed to:

Non-infectious hazards

SHOT Office
Manchester Blood Centre
Plymouth Grove
Manchester
M13 9LL

Tel +44 (0) 161 423 4208

Fax +44 (0) 161 423 4395

Website www.shotuk.org

Enquiries shot@nhsbt.nhs.uk

Email sue.knowles@nhsbt.nhs.uk
hannah.cohen@uclh.nhs.uk
alison.watt@nhsbt.nhs.uk
debbi.poles@nhsbt.nhs.uk
julie.ball@nhsbt.nhs.uk
hema.mistry@nhsbt.nhs.uk
tony.davies@nhsbt.nhs.uk

Infectious hazards

Ms Claire Reynolds
Scientist (Epidemiology)
Health Protection Agency
61 Colindale Avenue
London NW9 5EQ

Tel +44 (0) 20 8957 2920

Fax +44 (0) 20 8957 2884

Email epidemiology@nhsbt.nhs.uk

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Contents

1. Foreword

This is the 14th annual report of data collected and recommendations made by the SHOT UK Haemovigilance Scheme. In 2010, reports were submitted by 94.7% of National Health Service (NHS) hospitals or Trusts, and 91.4% of organisations reported incidents in all three broad categories (adverse events, near misses and physiological reactions). A total of 1464 reports were analysed, which represents a 14.5% increase from 2009, in addition to 863 instances of near miss and 137 right blood right patient (RBRP) incidents.

Notably, this is the first year in which there have been no confirmed cases of transfusion-transmitted infection (TTI). Furthermore there has been a 29% reduction overall in the number of incorrect blood component transfused (IBCT) reports: 57% less in the clinical area and 28% less in the laboratory. These figures indicate that efforts to train and competency assess clinical staff in transfusion, such as the National Patient Safety Agency (NPSA) Safer Practice Notice (SPN) 14,[1] are having an effect in the clinical area. In the laboratory the improvement is likely to be due to a combination of the requirements of meeting the Blood Safety and Quality Regulations (BSQR) 2005[2] and the recommendations of the UK Transfusion Laboratory Collaborative (UKTLC).[3]

However, transfusion-associated circulatory overload (TACO) and inappropriate and unnecessary (I&U) transfusions are becoming major issues and have been responsible for the majority of cases of mortality with imputability ≥2 (see Chapter 5, Summary of Main Findings and Cumulative Results, Chapter 6, Key Messages and Main Recommendations, and Chapter 2 for the definition of imputability).

Although there were only 3 deaths directly and solely caused by a transfusion (imputability 3), in a further 10 cases the transfusion probably (imputability 2) or possibly (imputability 1) contributed to the outcome. There were also 101 reports of major morbidity, with acute transfusion reactions (ATR) the single highest cause, resulting in a serious outcome for 7.8% of cases reported.

Changes to the SHOT 2010 Annual Report

This report has several changes from the 2009 report in that it includes a summary of mortality and morbidity, an analysis of near miss incidents, and a chapter related to the definitions of donor adverse events (see Chapters 5, 21 and 22, respectively). With respect to participation, only the overall participation rate and national figures are provided in the report, since each hospital or Trust will be benchmarked this year according to their issues of components. Recommendations from previous years and an update on their progress have now been posted on the website (www.shotuk.org).

Dr Hannah Cohen MD FRCP FRCPath

Chair, SHOT Steering Group

Dr Sue Knowles BSc FRCP FRCPath

Interim SHOT Medical Director

2. SHOT Reporting Categories and Definitions

The reporting categories have not changed since 2009 but a revised set of SHOT definitions of these categories is available on the website (www.shotuk.org).

Definitions

Imputability

The term 'imputability', as defined in the BSQR 2005, means 'the likelihood that a serious adverse reaction in a recipient can be attributed to the blood component transfused'.[1] A scale of 0 to 3 is also used in this report, as shown below:

0 =	**Excluded/unlikely**	The evidence is clearly in favour of attributing the reaction to other causes
1 =	**Possible**	The evidence is indeterminate for attributing the reaction to the blood or to alternative causes
2 =	**Likely**	The evidence is clearly in favour of attributing the adverse reaction to the blood or the blood component
3 =	**Certain**	There is conclusive evidence beyond reasonable doubt attributing the adverse reaction to the blood or blood component

Imputability should not be confused with severity. A very mild reaction, such as pyrexia with no associated symptoms occurring during a platelet transfusion, may have an imputability of 3. Conversely, an apparently 'severe' reaction may be associated with comorbidities and may have little to do with the transfusion in progress at the time and therefore have an imputability of 0 or 1. In sick patients with complex conditions it is at times very hard to ascribe imputability.

Transfusion-related mortality

- Death directly and solely caused by the transfusion reaction.
- Death to which the transfusion reaction probably contributed and which may not have occurred at that time had the reaction not taken place.
- Death that occurred at the time of or after a transfusion reaction, in which the reaction might have contributed to the death and it is not possible to exclude this.

These categorisations are made jointly by the reporter and the SHOT expert analyst. Inevitably such assessments may be a matter of informed opinion and there are times when this is an extremely hard judgement to make.

Major morbidity

The current categories of major morbidity used by SHOT are:

- intensive care or high-dependency admission and/or ventilation
- dialysis and/or renal impairment
- major haemorrhage from transfusion-induced coagulopathy
- jaundice, including evidence of acute intravascular haemolysis
- life-threatening acute reaction requiring immediate medical intervention
- persistent viral infection
- acute symptomatic confirmed infection
- sensitisation to D or K in a woman of childbearing potential
- reaction resulting in a low or high haemoglobin (Hb) level of a degree sufficient to cause risk to life unless there is immediate medical intervention.

Potential for major morbidity

- Potential risk of D or K sensitisation in a woman of childbearing potential.*

** This category has been amended by the SHOT Working Expert Group and Steering Group for 2010.*

3. Participation in the SHOT Haemovigilance Reporting Scheme

Introduction

The quality of SHOT data can only be assured if there is active engagement in the haemovigilance process by all participants. In 2010, 3200 reports were made to the scheme, of which 2464 were analysed. The remaining 736 reports were either withdrawn because they did not meet the SHOT criteria for reporting or were incomplete and will be included in the 2011 report. This represents a 14.5% increase in the number of analysed reports in comparison with 2009.

Number of reports by UK country

Table 1
Total number of reports to SHOT by UK country 2007–10

Country	2007		2008		2009		2010	
	Number	%	Number	%	Number	%	Number	%
England	1113	83.0	1816	83.4	1983	80.2	2511	78.5
Northern Ireland	45	3.3	68	3.1	70	2.8	154	4.8
Scotland	84	6.3	148	6.8	189	7.6	332	10.4
Wales	99	7.4	145	6.7	233	9.4	203	6.3
United Kingdom	**1341**	100.0	**2177**	100.0	**2475**	100.0	**3200**	100.0

Table 2
Total issues of blood components and solvent detergent-treated fresh frozen plasma for the calendar year 2010

Transfusion service	Red blood cells	Platelets	FFP	SD-FFP*	Cryoprecipitate*	Total
National Blood Service	1,836,489	204,112	249,509	48,186	101,496	2,439,792
Welsh Blood Service (WBS)	87,515	8,784	10,264	3,014	2,280	111,857
Scottish National Blood Transfusion Service (SNBTS)	203,423	27,153	26,275	4,200	11,520	272,571
Northern Ireland Blood Transfusion Service (NIBTS)	53,354	6,913	6,836	2,087	5,015	74,205
Total	**2,180,781**	**246,962**	**292,884**	**57,487**	**120,311**	**2,898,425**

** Figures for financial year 2009–10.*
FFP, fresh frozen plasma; SD-FFP, solvent detergent-treated fresh frozen plasma, Octaplas® manufactured by Octapharma Ltd.

The number of reports of physiological reactions should correlate with the number of components issued. Using the number of components issued as a comparator, the number of reports per 10,000 units has again increased, but there remains a difference in the rate of reporting by the four UK countries.

Table 3
Total number of reports per 10,000 components by UK country 2007–10

	2007	2008	2009	2010*	2010**
England	4.6	7.7	8.1	9.1	10.3
Northern Ireland	6.6	10.0	10.5	16.0	20.8
Scotland	3.1	5.4	6.8	10.6	12.2
Wales	8.4	12.3	19.6	15.2	18.1
United Kingdom	**4.8**	**7.8**	**8.5**	**9.6**	**11.0**

** Column 1 for 2010 reports is calculated using the total number of completed reports in 2010, which is directly comparable to the historical data.*
*** Column 2 for 2010 is calculated using the total number of reports that have been started in 2010 (3200), including those which are not completed and are therefore not analysed in the rest of this report. These figures are not directly comparable to historical data, but are more indicative of the actual participation in 2010 and will be used to monitor participation in forthcoming years.*

Total number of reporting organisations

The total number of reporting organisations has fallen from 255 in 2009 to 208 in 2010. This does not reflect a drop in participation, but is due to cleansing of the data taken from the Dendrite database, which has been undertaken to amalgamate individual reporters into their respective organisations. Of the 208 organisations reporting to SHOT, 179 are NHS organisations and 29 are independent hospitals or laboratories. However, Table 4 demonstrates that there are 10 UK organisations that did not submit reports in 2010, giving a participation rate of 97.4% in this sector.

Table 4
Organisation participation in the UK in 2010

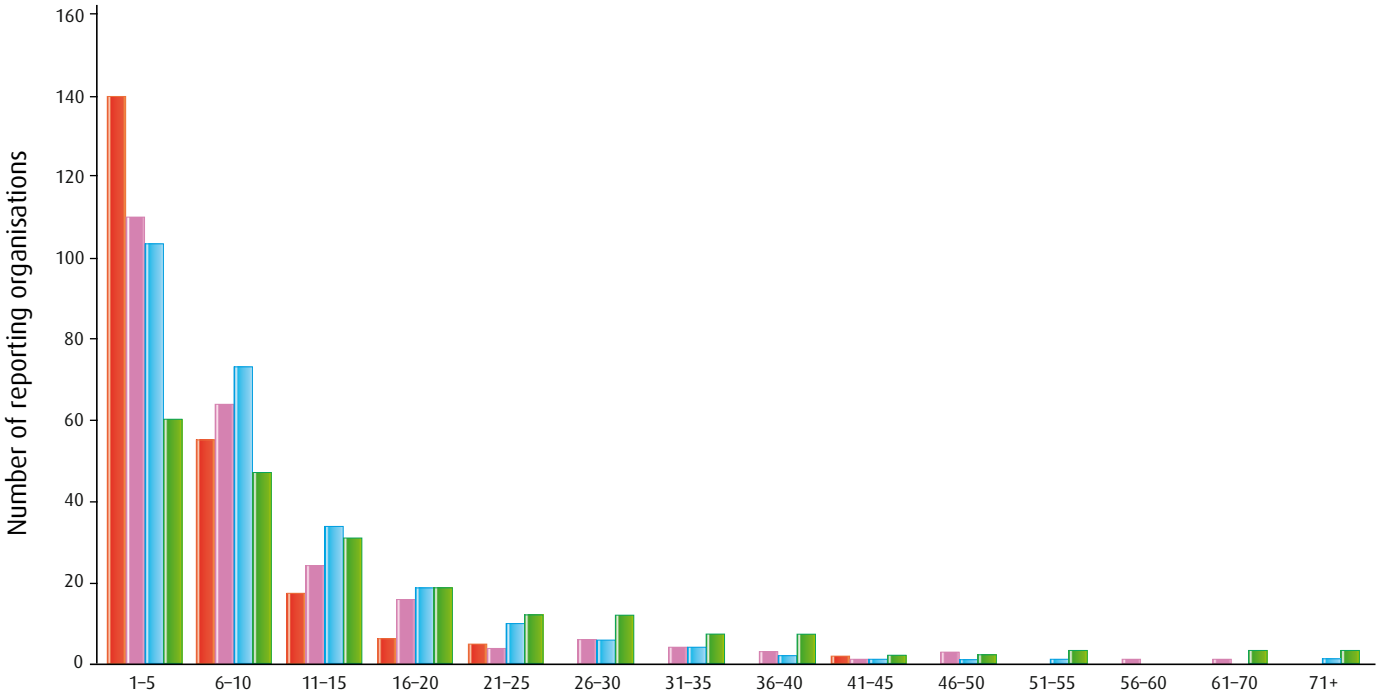
	No. of organisations	Organisations reporting on Dendrite	Non-reporting organisations
England	163	154	9
Northern Ireland	5	5	0
Scotland	15*	14	1
Wales	6	6	0
United Kingdom	**189**	**179**	**10**

** This figure includes 1 Special Health Board that has also made reports to Dendrite.*

Number of reports per reporting organisation by UK country in 2010

2010 has again seen an increase in the total number of reports, with a rising level of reporting by each participating organisation. A lower number of organisations have made fewer than 5 reports and there was a corresponding rise in the number of organisations making more than 25 reports (see Figure 3).

Figure 1
Number of reports sent per reporting organisation, UK



	1–5	6–10	11–15	16–20	21–25	26–30	31–35	36–40	41–45	46–50	51–55	56–60	61–70	71+
2007	140	55	17	6	5	0	0	0	2	0	0	0	0	0
2008	110	64	24	16	4	6	4	3	1	3	0	1	1	0
2009	103	73	34	19	10	6	4	2	1	1	1	0	0	1
2010	60	47	31	19	12	12	7	7	2	2	3	0	3	3

Types of incidents reported

For full participation, reporting organisations should ensure that all types of incidents are reported. Table 5 shows that some establishments have historically only reported in a narrow range of categories. However, the data show that there has been a marked improvement since 2007, with the vast majority of organisations now reporting in multiple categories.

Table 5
Analysis of types of incidents reported to SHOT

Category	2007	2008	2009	2010
Organisations which reported anti-D incidents only	3	2	2	0
Organisations which reported physiological reactions only	11	8	9	5
Organisations which reported adverse events and near misses only	116	103	32	3
Organisations which reported in multiple/other categories	88	121	206	190
Organisations which had all reports withdrawn	7	3	3	4
Organisations where all reports were incomplete*	Not applicable			6
Total	**225**	**237**	**252**	**208**

* *New category for 2010.*

Plans for benchmarking participation data

Individual participation data will be produced for each reporting organisation to enable users to monitor their own reporting frequency against comparable establishments.

Reporting organisations will be grouped in two separate ways:

- clustered by size according to their usage of blood components
- geographically, by UK country and grouped according to their Regional Transfusion Committee (RTC).

A summary report will be produced for each organisation showing their participation levels, split by category of report. There will also be comparisons made within each usage cluster and geographical group to enable an individual organisation to benchmark itself against its peers.

COMMENTARY

Although there has been an increase in the total number of reports submitted to SHOT, and more organisations are reporting all types of incidents, there are still 10 UK organisations who did not participate in the SHOT haemovigilance scheme during 2010.

Recommendation

There are no new recommendations.

For active recommendations and an update on their progress, please refer to the SHOT website.

4. SHOT 2010–11

Dendrite – the SHOT web-based reporting system

This system (www.n3-dendrite.com/shot) on the internet (or www.nhs-dendrite.com/shot on the NHSN3 network) has been in operation since 4th January 2010. It has been a significant advance with respect to the provision of data for the current and future annual reports. Since July 2010 the Dendrite database has been accessible through the N3 server, which has resolved many access and speed issues but not all locations in Wales have access to this server and these have needed to connect through the NHS Wales Informatics Service (NWIS). Comments and suggestions have been received from several participants for modifications and enhancements to the current system configuration.

The SHOT office distributed a user questionnaire in April 2011 to gauge current satisfaction with the system and to rank the comments and suggestions from reporters for modifications and enhancements. This feedback will be taken into account, together with that from the authors of SHOT chapters, to prioritise the Dendrite developments required for 2012.

The results of the Dendrite user survey are being presented at the SHOT annual symposium on 6th July 2011 and thereafter will be available under the Meetings section of the website.

Department of Health (DH) 'never events' list 2011–12[1]

SHOT and the National Blood Transfusion Committee (NBTC) communicated with the DH during its consultation to expand the list of 'never events'. These are defined as 'serious, largely preventable safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers'. This list now includes:

- Death or serious harm as a result of the inadvertent transfusion of ABO-incompatible blood components.

A second additional event is also pertinent, relating to the provision of blood and blood components in an emergency:

- In-hospital death of a mother due to postpartum haemorrhage (PPH) after elective Caesarean section (excluding where there is a pre-existing bleeding disorder or the mother refuses blood components for any reason).

Commissioners and providers are expected to discuss fully the circumstances of the event and to ensure that the lessons learnt are implemented. Commissioners also have the potential to cap the cost recovery of patient care required as a result of the incident.

UK Transfusion Laboratory Collaborative (UKTLC)

The recommendations of the UKTLC, which SHOT initiated and in which SHOT is a main collaborator, provide minimum standards for hospital transfusion laboratories and address staffing, technology, training and competence.[2,3] They are intended to encourage effective and appropriate use of technology and staff in hospital transfusion laboratories within the framework of current legislative requirements, and to achieve the minimum standards of proficiency and practice set by the Health Professions Council[4] and as required by the UK BSQR 2005.[5]

The Clinical Pathology Accreditation (UK) Ltd (CPA) support website now includes the recommendations as information considered useful for applicants currently preparing for an inspection visit and for assessors planning a visit in the near future. The recommendations were republished in a clarified format in the October 2010 issue of *The Biomedical Scientist*, with minor clarifications in response to feedback received in the previous 12 months that primarily relate to staff in post; these clarifications can be found on the Institute of Biomedical Science (IBMS) website.[6] A questionnaire survey of hospital laboratories to evaluate progress on implementation of the recommendations has been undertaken.

The results of this survey, circulated via the UK National External Quality Assessment Scheme for Blood Transfusion Laboratory Practice (UK NEQAS BTLP), will help to shape further updates or revisions of the recommendations. Work led by the IBMS on the development of a competency assessment scheme is in progress.

Since publication of the UKTLC recommendations, uptake for the British Blood Transfusion Society (BBTS) Certificate has increased, with the recommendations a likely major contributory factor. It is heartening to see a 28% decrease in laboratory-related errors in 2010 compared with those in 2009 (see page 28). Whilst several factors may be contributory, it is likely that the UKTLC recommendations are having an impact on hospital transfusion laboratories.

Benchmarking participation at organisation level

The Dendrite database has made it possible for individual organisation participation in SHOT to be benchmarked. At the time of writing the report, SHOT is in consultation with the National Transfusion/Advisory Committees over the content and format of this exercise and will be contacting reporters to provide further information later this year.

Update on 2009 recommendations

Last year SHOT made several recommendations and progress on these is highlighted below:

- **Laboratory and clinical information technology (IT) systems**
  The IT subgroup of the NBTC is currently surveying hospitals' use and/or plans for implementation of IT, including transfusion laboratory systems, bar-coded wristbands, wireless bedside IT, electronic blood fridges and electronic laboratory requesting. It will also seek to standardise requirements for blood transfusion in preparation for the implementation of the Clinical Records Service and take opportunities to link with other national patient safety initiatives using similar bedside technology.

- **Pulmonary complications of transfusion**
  A pulmonary complications subgroup convened by SHOT has considered various approaches to improve the understanding and classification of these reactions and the following have been proposed:

  1. Validation of the current approach of categorising cases of transfusion-related acute lung injury (TRALI).
  2. Constitution of a second expert panel to review potential transfusion-associated dyspnoea (TAD) and TACO cases on a regular basis since their distinction from ATR and/or TRALI can be difficult.
  3. It has been accepted that a Dendrite enhancement will be required to capture adequate information on all pulmonary cases to facilitate their correct classification, and that changes to this aspect of the database should be trialled during 2011.

- **Patient identification (ID)**
  A national patient education campaign has not materialised. However, the DH in its current list of 'never events' has included 'Death or severe harm as a result of administration of the wrong treatment following misidentification due to a failure to use standard wristband (or identity band) identification processes.'[1]

- **Clinical handover**
  It is well recognised that clinical handover carries risks arising from poor communication and systematic error. The Royal College of Physicians (RCP) conducted a survey of fellows and members in 2010, which was followed by a workshop dedicated to handover. From this work, a simple and pragmatic toolkit has been devised, which following consultation will be made available on the website. This toolkit will contain standards for the structure and content of a handover document developed by the RCP in 2008. The standards are evidence and consensus based, and templates and related implementation tools (e-learning tools, audit tools) are available at http://www.rcplondon.ac.uk/resources/clinical/medical-record-keeping.

- **Use of point of care testing (POCT) devices and blood gas analysers for Hb estimation**
  UK NEQAS (Haem) is currently designing a pilot external quality assurance scheme for the measurement of Hb by these analysers.

5. Summary of Main Findings and Cumulative Results

Figure 2
Cases reviewed in 2010 *n* = 1464

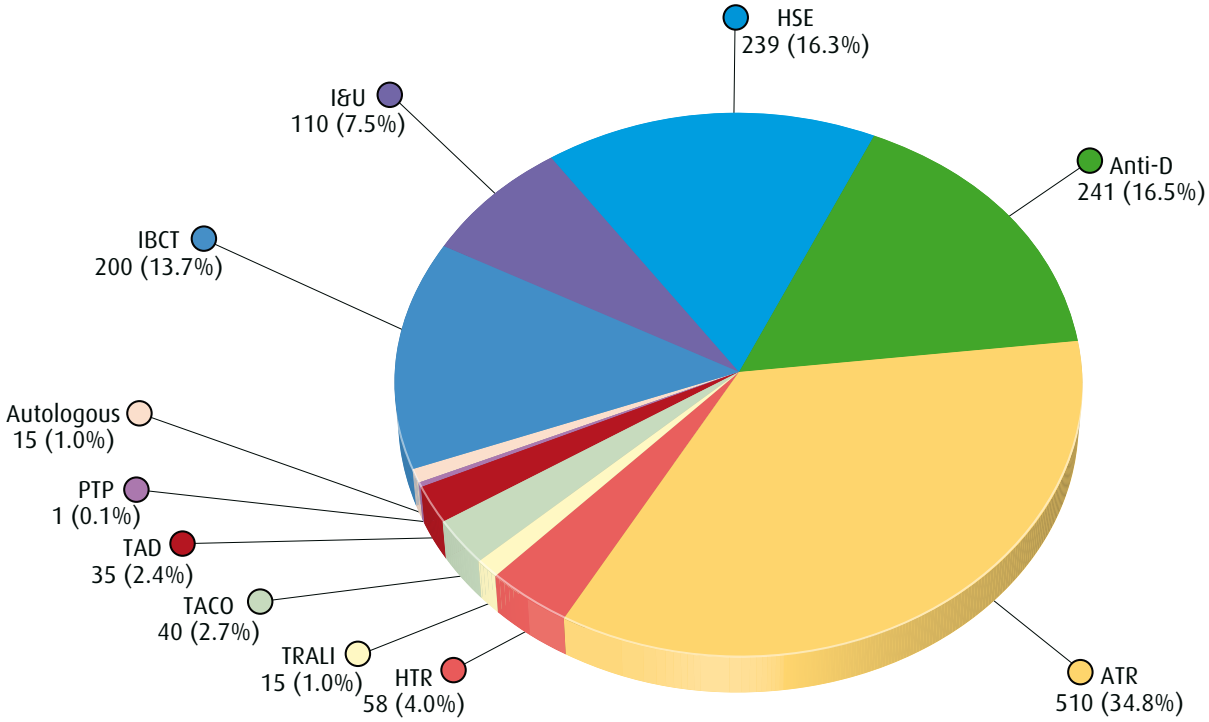


Figure 3
Trends in report types 1996–2010

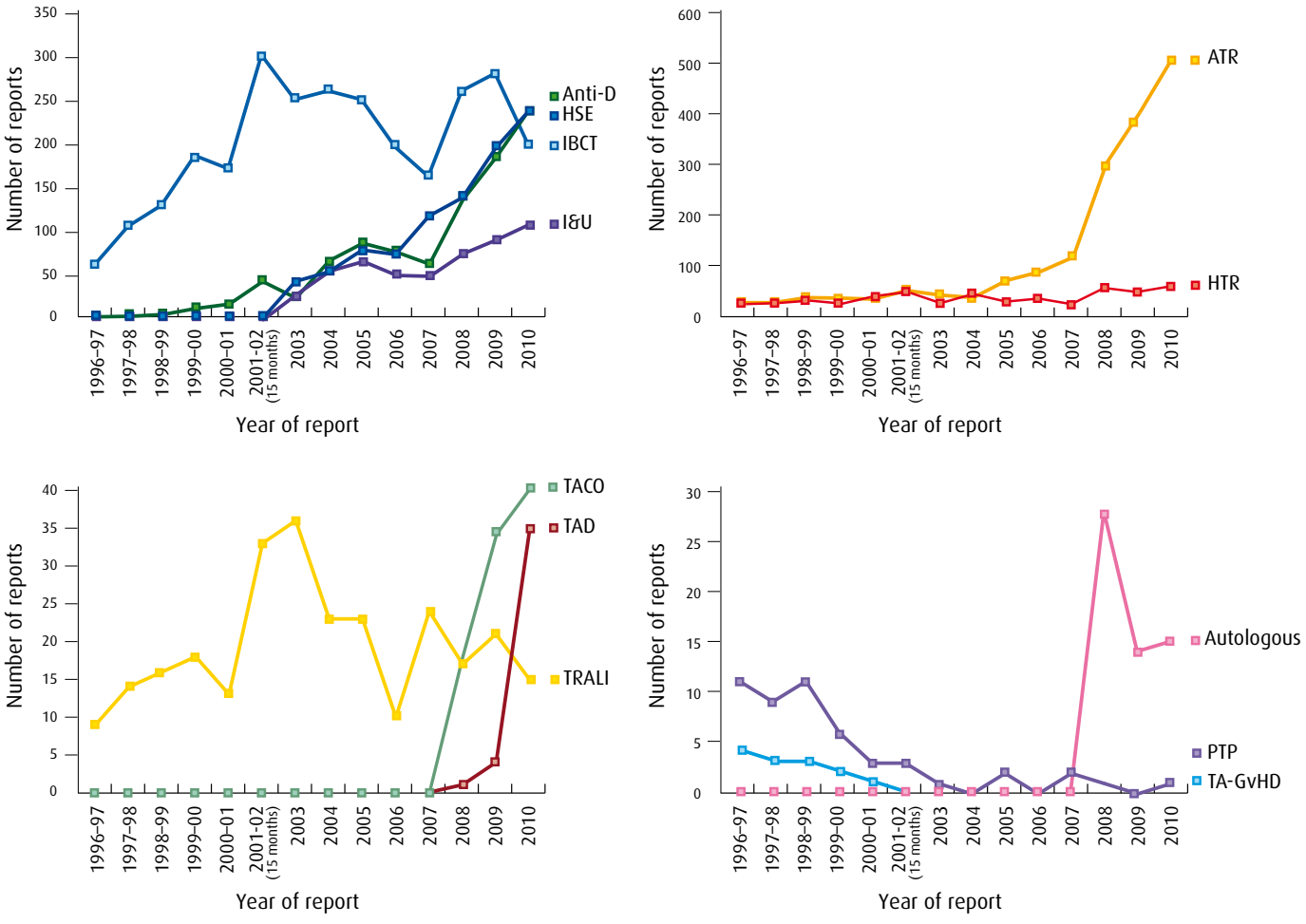


Table 6
Comparison of report types 1996–2010

Year/category	IBCT	I&U	HSE	Anti-D	ATR	HTR	TRALI	TACO	TAD	PTP	TA-GvHD	TTI	Auto-logous
2010	200	110	239	241	510	58	15	40	35	1	0	0	15
2009	282	92	196	186	400	47	21	34	4	0	0	3	14
2008	262	76	139	137	300	55	17	18	1	1	0	6	28
2007	164	50	118	63	114	23	24	0	0	2	0	3	0
2006	198	51	74	77	85	34	10	0	0	0	0	3	0
2005	252	67	79	87	68	28	23	0	0	2	0	5	0
2004	262	56	54	67	34	43	23	0	0	0	0	2	0
2003	252	29	43	24	39	25	36	0	0	1	0	9	0
2001/2002*	303	0	0	43	48	47	33	0	0	3	0	6	0
2000/2001	173	0	0	17	31	39	13	0	0	3	1	6	0
1999/2000	188	0	0	12	33	24	18	0	0	6	2	6	0
1998/1999**	131	0	0	5	34	30	16	0	0	11	3	9	0
1997/1998	107	0	0	3	24	25	14	0	0	9	3	3	0
1996/1997	63	0	0	0	24	23	9	0	0	11	4	8	0
Total	**2837**	**531**	**942**	**962**	**1744**	**501**	**272**	**92**	**40**	**50**	**13**	**69**	**57**

** 2001/2002 figures cover a 15-month period. ** Total excludes 7 cases that were not classified.*
TA-GvHD, transfusion-associated graft versus host disease.

This year has seen a further change in the pattern of reports submitted to SHOT. There have been no cases of TTIs and the number of reports of 'wrong blood' (IBCT) has fallen by 29% overall: 57% less in the clinical area and 28% less in the laboratory. These figures indicate that efforts to train and competency assess clinical staff in transfusion, such as the NPSA SPN 14, are having an effect in the clinical area. In the laboratory the improvement is likely to be due to a combination of the requirements of BSQR 2005 and the recommendations of the UKTLC.

Of 1464 reports with the potential for mortality and morbidity, there were 13 deaths and 101 cases of major morbidity, resulting in a serious outcome for 7.8% of cases reported. Of these 13 deaths, 3 were solely as a result of the transfusion (imputability 3), 3 were probably due to the transfusion (imputability 2) and 7 possibly due to the transfusion (imputability 1).

Further information about these cases and additional learning points can be found in the relevant chapters of this report.

Deaths *n* = 13

ATR *n* = 3

Of the 3 deaths in this category, there was 1 case of sudden unexpected death during a red cell transfusion. Although there were no diagnostic changes on post-mortem examination, the death was attributed to an anaphylactic reaction on the basis of mast cell tryptase (MCT) levels on a post-mortem specimen (imputability 3).

This adverse reaction presents a challenge since although it occurs most frequently during the first 15 minutes of transfusion (mean time to onset of 26 minutes in the cases reported in 2010), there is a risk throughout the transfusion episode. This emphasises the requirement for regular visual observation of patients during the transfusion episode and that patients must only be transfused where there are facilities to recognise and treat this reaction.

Learning points

- Transfusion should only take place if there are sufficient competent staff available to monitor the patient and the patient can be readily observed throughout the transfusion episode.
- Transfusion should only be performed where there are facilities to recognise and treat anaphylaxis.

The possibility that severe ATRs had contributed to death could not be excluded in 2 patients (imputability 1).

- A septic neonate suffered a cardiac arrest during the transfusion of apheresis platelets and died 2 hours later.
- An adult patient with a cerebral tumour developed hypertension and rigors during the transfusion of apheresis platelets and died several hours later, following a bleed into the tumour.

HTR *n* = 1

Hyperhaemolysis in sickle cell disease *n* = 1

A death occurred in a child with sickle cell disease who suffered from hyperhaemolysis as a result of the transfusion. This is an uncommon though well-recognised complication in which further transfusions can exacerbate the haemolysis and lead to a chronic protracted course or even death.

Learning point

- A hyperhaemolytic transfusion reaction should be suspected if the patient develops a more marked anaemia than was present pre-transfusion. Expert advice should be sought from a specialist sickle cell unit or the Blood Service.

TACO *n* = 6

Of these 6 deaths, 1 was solely due to the transfusion (imputability 3), 3 were probably/likely to be due to the transfusion (imputability 2) and in 2 the possibility that TACO had contributed to death could not be excluded (imputability 1). This adverse reaction, which is under-recognised and under-reported, has an incidence of approximately 6–8% in patients in intensive care.[1] While not all patients at risk of TACO can be identified, recognised patient factors which predispose to this condition include cardiac and renal impairment, hypoalbuminaemia and pre-existing fluid overload, and its development is dependent on both the rate and volume of transfusion. Recommendations related to this adverse reaction are outlined in Chapter 6.

Learning point

- In those patients predisposed to TACO, careful assessment must be made of their pre-transfusion fluid balance status and the tolerable rate of transfusion.

I&U and under/delayed transfusion *n* = 2

I&U transfusion *n* = 1

A death occurred in an elderly patient with gastrointestinal (GI) haemorrhage and an Hb of 10.6 g/dL who was transfused with 5 units of red cells prior to rechecking the Hb. The patient developed TACO and died shortly afterwards (imputability 1). This case is one of several where more frequent monitoring of the Hb should have been required in patients with modest but ongoing blood loss.

Learning point

- In patients with modest but ongoing blood loss, frequent monitoring of the Hb is essential.

Delayed transfusion *n* = 1

A death occurred in a patient with massive GI blood loss who was given 10.5 L of colloid but only 4 units of red cells over a period of 1.5 hours in the accident and emergency (A&E) department prior to death. The lack of adequate blood component support was thought to have possibly contributed to the outcome (imputability 1). This case demonstrated the lack of familiarity with the Trust Major Haemorrhage Policy, which in turn did not take into account the need for rapid availability of all blood components.

Learning point

- Every Trust must review its Major Haemorrhage Policy to ensure that it is compliant with the recommendations of the NPSA Rapid Response Report 'The transfusion of blood and blood components in an emergency' NPSA/2010/017.[2]

TRALI *n* = 1

A patient with upper GI bleeding received a massive transfusion and died later the same day of cardio-respiratory failure. A patient sample was unavailable for complete investigations and consequently the imputability of this case is 1.

Table 7
Cumulative mortality/morbidity data 1996–2010
NB TACO, TAD and autologous are new since 2008, and HSE and I&U were separated from IBCT in 2008.

	Total	IBCT	I&U	HSE	Anti-D	ATR	HTR	TRALI	TACO	TAD	PTP	TA-GvHD	TTI	Auto-logous
Death in which transfusion reaction was causal or contributory	151	27	6	0	0	22	12	43	11	0	2	13	15	0
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	596	118	7	0	26	115	50	178	33	7	13	0	48	1
Minor or no morbidity as a result of transfusion reaction	7348	3637	265	574	601*	1604	438	51	48	33	35	0	6	56
Outcome unknown	15	11	0	0	0	3	1	0	0	0	0	0	0	0
Total**	**8110**	**3793**	**278**	**574**	**627**	**1744**	**501**	**272**	**92**	**40**	**50**	**13**	**69**	**57**

** Cases with potential for major morbidity are included in minor or no morbidity.*
*** Total excludes 7 cases from 1998–99 that were not classified.*

Table 8
Mortality/morbidity data 2010

	Total	IBCT	I&U	HSE	Anti-D	ATR	HTR	TRALI	TACO	TAD	PTP	TA-GvHD	TTI	Auto-logous
Death in which transfusion reaction was causal or contributory	13	0	2	0	0	3	1	1	6	0	0	0	0	0
Major morbidity probably or definitely attributed to transfusion reaction (imputability 2/3)	101	2	4	0	1	57	2	13	15	6	0	0	0	1
Minor or no morbidity as a result of transfusion reaction	1350	198	104	239	240*	450	55	1	19	29	1	0	0	14
Total	**1464**	**200**	**110**	**239**	**241**	**510**	**58**	**15**	**40**	**35**	**1**	**0**	**0**	**15**

** Cases with potential for major morbidity are included in minor or no morbidity.*

Major morbidity *n* = 101

ATR *n* = 57

There were 57 reports in which the symptoms and signs of the transfusion reaction were sufficiently severe to imply that delay in treatment could be life-threatening. These included 34 cases of anaphylactic and 1 angioedema reactions, 11 allergic reactions with bronchospasm, 10 cases of hypotension (including 2 cases of transfusion associated with the onset of dysrhythmias) and 1 supraventricular tachycardia with a fever.

TACO *n* = 15

Of these patients, 13 required intensive therapy unit (ITU) admission and/or ventilation. The remaining 2, who were already on ITU, required increased ventilatory support after the development of TACO.

TRALI *n* = 13

All cases by definition had been hypoxic with bilateral pulmonary infiltrates on chest X-ray (CXR), requiring treatment on ITU.

TAD *n* = 6

There were 6 cases that required ITU admission and/or ventilation.

I&U transfusions *n* = 4

These patients were over-transfused for the following reasons:

- in 1 case because of wrong blood in tube (WBIT)
- in 1 case because of transfusing 6 units of red cells to a patient with a GI bleed without any interim monitoring
- in 1 case because of failure to take into account the low body weight of the patient when prescribing red cells
- in the final paediatric case, due to the entire unit being transfused on account of a roller clamp connected to the pack not being fully closed.

Of these, 2 developed TACO, 1 of which was venesected and a third sustained a cerebral infarct.

IBCT *n* = 2

One patient given an ABO-incompatible transfusion required admission to ITU because of intravascular haemolysis and renal failure. A second female patient of childbearing potential was transfused with K positive red cells and became alloimmunised.

HTR *n* = 2

One patient with a delayed haemolytic transfusion reaction (DHTR) required admission to ITU and a second developed renal impairment.

Anti-D *n* = 1

In 1 case an RhD negative female patient aged 18 years developed anti-D after receiving RhD positive platelets during a trauma-associated transfusion, for which no anti-D immunoglobulin (Ig) prophylaxis was administered.

Autologous *n* = 1

One patient who had an emergency Caesarean section developed a severe coagulopathy following the reinfusion of 1110 mL of salvaged blood and required further blood components and was also given rVIIa.

6. Key Messages and Main Recommendations

Too much blood, too quickly or too little, too late

This year's report has witnessed a continuing shift away from the numbers of reports submitted of 'wrong blood', IBCT, towards cases where patients have been transfused with too many red cells, given their underlying co-morbidities, body weight or blood loss, or where there has been a failure to adequately monitor the patient's vital signs or Hb response during the transfusion. In total 4/6 deaths of imputability ≥2, 2/7 deaths of imputability 1 and 19 instances of major morbidity have been caused by TACO or over-transfusion. SHOT has requested reports of under- or delayed transfusion, and although only 2 reports have been submitted (and it is recognised that there is substantial under-reporting), both show a lack of understanding of the requirement to make blood components rapidly available for patients with massive haemorrhage in line with the recommendations of the NPSA Rapid Response Report 2010/017.[1]

The implementation of NPSA SPN 14, Right Patient, Right Blood[2]

It is likely that this SPN and other efforts to train and competency assess clinical staff in transfusion are having an impact on reducing the numbers of instances of IBCT. However, the recent survey on the implementation of the Health Service Circular (HSC) 2007/001 in England and North Wales has shown that only 77% of Trusts have provided competency-based training and assessment for blood administration for 50–91% of staff.[3] Furthermore, the 2010 National Transfusion Practitioner Survey of England and North Wales has emphasised that the vast majority of their time is spent on ensuring compliance with NPSA SPN 14 and BSQR 2005, to the detriment of other aspects of transfusion safety or inappropriate use. This is a critical factor in 25% of transfusion practitioners being dissatisfied with their role. Furthermore, one-third of respondents commented that they receive little support from managers and the Trust in general.[4]

Given the inclusion of 'Death or serious harm as a result of the inadvertent transfusion of ABO-incompatible blood components' in the DH 'never events',[5] it is imperative that the practical aspects of implementing NPSA SPN 14 are reviewed in accordance with the five key steps issued jointly by NPSA, NBTC and SHOT in December 2009 and that hospitals/Trusts ensure that their transfusion committees and teams are adequately resourced.[6]

Recommendation

- There should be a review of the practical aspects of the implementation of NPSA SPN 14 and other national transfusion competency initiatives with a view to new guidance being issued and that Trusts should ensure that individual transfusion practitioners are fully supported with the allocation of additional link nurses in the escalation of training and assessment.

  Action: NBTC, Trust/hospital chief executive officers (CEOs)

The medical assessment and management of patients receiving blood transfusions

Numerous reports this year in the TACO and the I&U (see Chapters 14 and 8) have shown that there is inadequate medical assessment of patients during the prescription and monitoring of transfusion episodes. Salient findings include the following:

- Lack of attention to fluid balance, particularly in elderly patients >70 years and those with concomitant medical conditions that predispose to TACO: cardiac failure, renal impairment, hypoalbuminaemia and fluid overload.
- A lack of appreciation that the rate of transfusion is another risk factor in the development of TACO.

- There is over-transfusion due to a lack of consideration of the patient's body weight when prescribing red cells. While there is uncertainty over the correct dose of red cells given the weight of the patient, the notion that 1 unit of red cells gives an increment of approximately 1 g/dL Hb can at best only be applied to a 70–80 kg patient and for patients of lower body weight the prescription should be reduced.
- There is over-transfusion in patients with minor but ongoing blood loss, owing to the lack of regular monitoring of the Hb after every 2 or 3 units of red cells.

Recommendations

- The existing British Committee for Standards in Haematology (BCSH) guidelines for the Administration of Blood Components[7] should be supplemented by an amendment dealing with measures to avoid the development of TACO and over-transfusion, particularly in vulnerable patients, including pre-transfusion clinical assessment, rate of transfusion, fluid balance, regular monitoring of Hb and prescription of diuretics.

  Action: BCSH Transfusion Taskforce

- There should be a systematic review of the application of weight-related empirical formulae or algorithms in prescribing for low body weight adults.

  Action: NHSBT

Clinical knowledge and handover

There is evidence in this year's report that although some prescribing errors are undoubtedly due to a lack of junior staff's knowledge of transfusion medicine, there are also many instances where it is clear that the doctor has insufficient information about the patient in question. Previous test results or decisions documented in the notes concerning the need for transfusion are overlooked, and prescriptions are made for the wrong patient or the wrong component.

With respect to training, requests from the Royal Colleges/Specialist Societies subgroup of the NBTC to the Postgraduate Medical Education and Training Board (PMETB) and the General Medical Council (GMC) for the inclusion of blood transfusion in undergraduate teaching and Foundation Year (FY) competencies have been unsuccessful. However, to limit avoidable patient morbidity and mortality arising from blood transfusion it is essential that knowledge of prescribing blood components is recognised as a core requirement.

Furthermore, clinical handover templates should include the decisions taken for future management of the patient, including planned transfusion support.

Recommendations

- Transfusion medicine must be part of the core curriculum for doctors in training.

  Action: Education working groups of national transfusion committees

- To avoid inappropriate and unnecessary transfusions due to lack of adequate clinical handover, decisions made concerning the need for transfusion support should be documented in the clinical handover templates.

  Action: Trusts/hospitals

Rapid Response Report NPSA/2010/017[1]

SHOT fully supports the content of this publication related to the transfusion of blood and blood components in an emergency, which requires local robust protocols outlining the need for clearly understood communication channels between the clinical area and the laboratory, and the actions to be taken by both parties.

While these events are reportable to SHOT under the I&U/Delayed and Under-transfusion category and reporters are encouraged to continue reporting to SHOT, the current Dendrite database could usefully be enhanced to fully capture the details of these events.

Recommendations

- All under- and delayed transfusions that have a significant impact on patient outcomes should be reported to SHOT.

  Action: Hospital transfusion teams (HTTs)

- The Dendrite database should be enhanced to fully capture the salient clinical features and details of the timeliness of blood component support.

  Action: SHOT team

Improving laboratory standards

SHOT supports the recommendations of the UK Transfusion Laboratory Collaborative with regard to hospital transfusion laboratory staffing, technology, training and competencies.[8,9] Incidents analysed in this and previous SHOT reports add weight to the Collaborative's recommendations for training programmes and annual competency assessment for *all* staff who work at any time in the transfusion laboratory. There is particular emphasis on maintaining competency, including familiarity with local protocols and systems, of staff working intermittently in the transfusion laboratory. SHOT supports the recommendations on the routine use of 'walk away' automation, used 24/7, to eliminate manual errors and the use of electronic issue (EI) of red cells, where the laboratory information management system (LIMS) fully meets national guideline standards. Full vein-to-vein electronic blood tracking, where *remote issue* of blood components is introduced, will make a significant contribution to transfusion safety. Adequate resources will need to be made available to allow these improvements to occur.

Recommendations

- Trusts should implement the recommendations of the UK Transfusion Laboratory Collaborative.

  Action: Trusts/hospitals

- Work should continue with suppliers of LIMS to improve the capability of IT systems to generate warning flags and implement component selection algorithms based on data incorporated in the component label. These improvements should be in line with the recommendations of the BCSH guidelines on laboratory IT systems currently in preparation.

  Action: Manufacturers of laboratory IT systems

7. Incorrect Blood Component Transfused (IBCT)

Definition

The category incorrect blood component transfused comprises all reported episodes where a patient was transfused with a blood component that was intended for another patient or which was incorrect in terms of its specification.

DATA SUMMARY

Total number of cases	**200**

Implicated components	
Red cells	**163**
FFP	**8**
Platelets	**18**
Red cells + platelets	**9**
Other (granulocyte)	**1**
Unknown	**1**

Mortality/morbidity	
Deaths due to transfusion	**0**
Deaths *probably/likely* due to transfusion	**0**
Deaths *possibly* due to transfusion	**0**
Major morbidity	**2**

Gender	
Male	**99**
Female	**95**
Unknown	**6**

Age	
≥18 years	**168**
16 years to <18 years	**2**
1 year to <16 years	**15**
>28 days to <1 year	**5**
Birth to ≤28 days	**9**
Not known	**1**
Total	**200**

Emergency vs. routine and core hours vs. out of core hours	
Emergency	**44**
Routine	**131**
Not known	**25**
In core hours	**148**
Out of core hours	**41**
Not known	**11**

Where transfusion took place	
A&E	**7**
Theatre	**12**
ITU/NNU/HDU/recovery	**24**
Wards	**135**
Community	**4**
Medical admissions units	**7**
Outpatient/day unit	**7**
Not known	**4**

NNU, neonatal unit; HDU, high-dependency unit.

In keeping with the previous 2 years' reports this chapter is confined to the following errors in the transfusion process:

- phlebotomy errors resulting in WBIT
- collection and administration errors
- laboratory procedural and testing errors
- transfusion of components not meeting the patient's special requirements (SRNM).

In 2010, a total of 200 IBCT reports were received, which represents a 29% fall in comparison with 2009, when 282 reports were analysed.

The chapter is divided into four sections: clinical errors, laboratory errors, those related to IT systems and RBRP incidents. The data given in this chapter include paediatric cases, but these are described in more detail on page 121.

Table 9
Numbers of true IBCT cases and rate per 100,000 blood components issued 2003–10

Year	No. of cases reported on IBCT questionnaires	Reports per 100,000 components
2003	252	7.4
2004	262	7.8
2005	252	8.1
2006	198	6.6
2007	164	5.6
2008	262	9.2
2009	282	9.7
2010	200	6.9

NB These figures exclude HSE and I&U; these are not categorised as IBCT and are reported in separate chapters.

Figure 4
IBCT cases 1996–2010 showing ABO-incompatible red cell transfusions

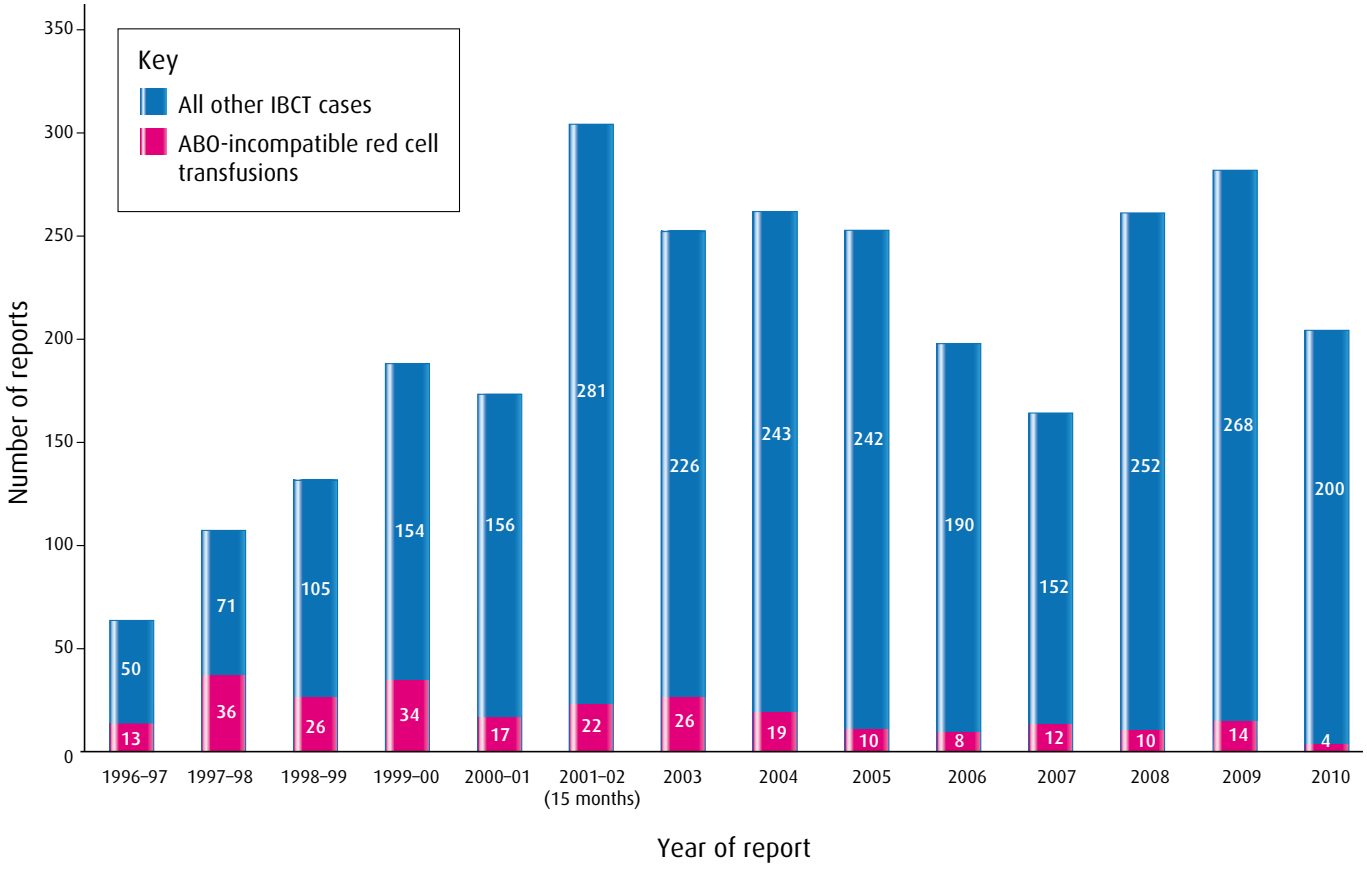


Table 10
Summary of IBCT cases

Type of event	No. of cases 2009		No. of cases 2010	
Administration of wrong blood component		**40**		**16**
ABO-incompatible red cells	8		2	
RhD-incompatible red cells	1		1	
ABO- and RhD-incompatible red cells	2		0	
Compatible red cells	21		0	
Others	8		13	
WBIT		**4**		**3**
ABO-incompatible red cells	2		1	
RhD-incompatible red cells	1		2	
Compatible red cells	1		0	
Laboratory errors leading to:		**5**		**3**
ABO-incompatible red cells	2		1	
RhD-incompatible red cells	3		2	
Compatible but wrong group red cells selected for stem cell transplant (SCT) patient		**13**		**15**
Other pre-transfusion testing errors		**64**		**52**
Special requirements not met (SRNM)(clinical)		**87**		**74**
SRNM (laboratory)		**67**		**37**
Miscellaneous IBCT		**2**		**0**
Total		**282**		**200**

SUMMARY OF KEY DATA FOR ALL IBCT CASES *n* = 200

Mortality *n* = 0
There were no fatal cases from IBCT this year.

Major morbidity *n* = 2
There was 1 case of major morbidity following an ABO-incompatible transfusion due to a collection error not detected at the bedside and 1 relating to the development of anti-K in a woman of childbearing potential who was transfused with K+ red cells.

ABO-incompatible red cell transfusions *n* = 4
Of a total of 4 ABO-incompatible transfusions, 1 due to WBIT, 2 due to collection errors not picked up at the bedside and 1 due to a grouping error.

RhD-incompatible red cell transfusions *n* = 5
There were 2 cases as a result of WBIT, 1 due to transfusing a patient for whom no blood was prescribed and 2 due to grouping errors.

WRONG BLOOD INCIDENTS ORIGINATING IN THE CLINICAL AREA *n* = 19

Overview

Nineteen cases were reported in this subcategory this year. This is a 57% reduction in clinical errors in 2010 in comparison with 2009. Ten out of the 19 cases were where the transfusions occurred during routine working hours in contrast with previous years, with only 4 transfusions given as an emergency. Eight reports were related to male patients and 11 to female patients. Two reports involved paediatric patients aged under 28 days old, who were transfused adult O RhD negative red cells in an emergency situation. In one case O RhD negative adult 'flying squad' red cells were collected from the satellite blood fridge and transfused and in the second case a unit of O RhD negative blood was given that had been crossmatched for an adult obstetric patient.

Table 11
Summary of clinical wrong blood errors

Type of error	No. of cases in 2009	No. of cases in 2010
WBIT	4	3
Collection and administration	16	7
Administration alone	14	8
No information provided to the laboratory concerning the required group change following SCT	4*	1
Others	6	0
Total	**44***	**19**

**Included under SRNM in 2009.*

Table 12
Summary of ABO- and RhD-incompatibilities resulting from clinical wrong blood errors

Incompatibilities	No. of cases in 2009	No. of cases in 2010
ABO-incompatible	8	3
RhD-incompatible	1	3
ABO- and RhD-incompatible	2	0
ABO- and RhD-compatible	21	13

Mortality

There were no fatalities in this group that were directly attributable to transfusion.

Major morbidity

There was 1 case of major morbidity reported as a result of an ABO incompatible transfusion.

Case 1

Lack of correct final identity check leads to an HTR

A patient with a haematemesis was in need of an urgent blood transfusion. The patient's wristband was contaminated with blood and could not be read, and as a consequence the electronic bedside checking system was not used. The compatibility form filed in the patient's notes, which belonged to another patient, was used to provide the identifiers for collecting the blood. The patient, who was group O RhD positive, was transfused with >50 mL of A RhD positive red cells prior to the error being recognised. The patient was admitted to ITU with intravascular haemolysis and renal impairment.

The errors in this case were due to both the collection and administration of the transfused unit. Both tasks were completed by one nurse, who identified the patient using a misfiled compatibility form, which should never be used as part of the final patient identity check. In an emergency situation, particular vigilance is essential to ensure that the correct patient is being transfused.

ABO- and/or RhD-incompatible transfusions *n* = 6

In addition to the case described above, 1 group B RhD positive patient received 2 units of A RhD positive blood as a result of WBIT and suffered no adverse outcome. An O RhD positive patient received 1 unit of A RhD positive blood as a result of a combination of collection and administration errors, again with no reported adverse outcome.

Two RhD-incompatible transfusions were the result of WBIT and the third was due to the administration of blood to a patient for whom there was no prescription. None was female of childbearing potential, but 1 was noted to have developed anti-C+D+K on the next occasion.

Case 2

Incident only discovered after a letter of complaint to the CEO

An elderly patient (group O RhD negative) had a postoperative cell salvage drain in situ following a total knee replacement (TKR). There was no prescription for allogeneic (donor) blood. The patient was wearing the correct wristband. Despite the lack of a prescription, the patient was transfused out of hours with 1 unit of O RhD positive red cells allocated to another patient. The patient's daughter complained to the CEO.

This case demonstrates a complete non-compliance with the transfusion process in transfusing a patient without a prescription, transfusing out of hours in a non-urgent situation, and collecting and administering a unit of blood without correctly identifying the patient.

Combined blood component collection and administration errors *n* = 7

Collection of the incorrect blood component from the fridge will lead to a wrong blood component being transfused if the final administration check does not include positive ID of the patient. It is disappointing to note that in 5 of the 7 cases, the staff member collecting the component had been trained and competency assessed.

Case 3

Incomplete checking of core identifiers leads to incorrect component collection and administration

A patient who was group O RhD positive shared the same forename and surname as a group A RhD positive patient in another ward, for whom blood had also been issued. The staff member collecting the unit, who had been trained but not competency assessed, had been given a collection slip with the patient's full identifiers. Nevertheless, the incorrect unit was collected and the patient was not positively identified at the bedside. The group O RhD positive patient received 1 unit of A RhD positive red cells and the error was not appreciated until the second unit was required 12 hours later. The patient suffered no adverse outcome.

Transposition of units collected simultaneously for two patients *n* = 4

When components are collected for more than one patient, there is the potential for transposing these units unless there is strict adherence to the final bedside administration check. Examples were reported from haematology day wards and ITU.

Evidence of wristbands

In 13 out of 19 cases the patient was documented as wearing a wristband but in 2/13 cases the patient details were incorrect. In the remaining cases, no information is provided.

Total bedside administration errors *n* = 16

(Including 7 following on from the collection of the incorrect component)

With the exception of the 3 reports due to WBIT, all other cases of IBCT were due to a failure to satisfactorily complete the final administration check at the bedside. In 9/16 cases two staff members checked the unit prior to administration to the patient, in 3/16 cases a one-person check was completed by a registered nurse/midwife and in 1/16 cases the check was made by a junior doctor alone. In 2 cases there was no information.

Table 13
Details of final administration check

Checks reported	No. of cases
Compatibility form alone	1
Compatibility form and prescription	2
Patient ID band (and/or verbal confirmation), compatibility form and prescription	3
Doctor asked confused patient to confirm their details	1
Limited checks in emergency situation	3
No checks at all reported	5
Unknown	4

The following witness account illustrates the need to conduct the final administration check at the bedside. A cross-check of the details of the unit of blood against the compatibility form or the prescription at a remote location does not serve any purpose in ensuring that the correct patient will be transfused.

Case 4

Checking the documentation and the unit of blood remotely from the bedside does not identify the patient

Two patients on the ward required transfusing. Blood was collected from the fridge for the patient. Cross-checks were made with the documentation and the bag of blood, and found to be correct. Blood ran through and taken to patient's bedside. Turned the blood on and it wasn't running so flushed cannula again. It worked but found it positional so placed the patient's arm on a pillow. The blood was dripping fine then. Walked around to document on the fluid balance chart how much blood was in the bag and noticed it was the wrong patient. Realised then that the patient's name band had not been checked prior to connecting the blood. Turned the blood transfusion off immediately (approximately 10 mL maximum would have been received).

Table 14
Volume of wrong component transfused

Volume given	No. of cases
<50 mL	5
50–99 mL	1
100 mL	1
Whole unit	6
>1 unit	3
Unknown	3

In 5/19 cases the recipient received <50 mL. In 3/5 cases the person administering the blood noticed the error after commencing the transfusion and in 2/5 cases blood had been collected for 2 patients at the same time and was given to the incorrect patient. The error was then realised when the staff came to administer blood to the second patient.

COMMENTARY on clinical wrong blood errors

The marked decrease in the number of reports submitted to this category in 2010 is likely to be due to the implementation of NPSA SPN 14 'Right patient, right blood' and other initiatives to train and competency assess clinical staff in transfusion.[1]

Although there were only 3 WBIT errors this year that led to the incorrect component being transfused, it is apparent from the near miss reports analysed (see Chapter 21) that 386/863 reports relate to WBIT and that this remains the most common potential weakness in the process. WBIT errors constitute an area of significant concern since if there is no laboratory record of a historical group, there is no opportunity during the subsequent procedure for their detection.

There has been a reduction in the number of reports in which the first error was made at the time of collecting the unit. However, despite training and competency assessment, there are examples of staff apparently not being aware of the fundamental importance of checking all patient identifiers rather than only relying on the first and family names.

While there has also been a reduction in the number of wrong blood bedside errors this year, there is evidence from these reports of misconceptions over the correct procedure and practice, and evidence of non-compliance with the BCSH guidelines on the Administration of Blood Components.[2] It is important that all staff are conscious that the final bedside check is the essential step to confirm the identity of the patient and provides the last opportunity to prevent an incorrect blood component being transfused to a patient. If two members of staff are assigned to complete this check, then each person should complete the checks independently.

It is also disappointing to note that despite the statement in NPSA SPN 14[1] that the compatibility form must not be used in the final bedside check of patient identity, this practice is still evident.

Learning points

- In a non-urgent situation, components must not be transfused that are not prescribed.
- Components should whenever reasonable be collected for one patient at a time to prevent their transposition to the incorrect patient.
- All Trusts/Boards must incorporate the recommendations of the BCSH guidelines on the Administration of Blood Components into local transfusion policies.

Learning points from 2009 that remain relevant

- No wristband – no transfusion.
- The compatibility form must not be used as part of the patient ID check.
- The patient must be physically present when the ID check is carried out. Any other check is not a patient ID check.
- Patient ID is an absolutely fundamental part of the delivery of healthcare in any discipline, and should be second nature to all staff.
- It is crucial that the content and principles contained in any training and competency package are fully appreciated and understood if errors are to be avoided.

CLINICAL CASES OF SRNM *n* = 74

A total of 74 clinical SRNM reports were analysed this year.

This year there were 40 male and 33 female patients and 1 case where the gender was not specified. Five cases involved paediatric patients (discussed in further detail in Chapter 20). As in previous years, the majority of cases where special requirements were not met related to the provision of irradiated components. With 3 exceptions (renal transplant patients who had received Campath), reports of patients requiring but not receiving irradiated components had been or were still under the care of a haematologist.

Table 15
SRNM where the error was clinical

Category of error	No. of clinical cases
Irradiated	59
Cytomegalovirus (CMV) negative	7
Irradiated and CMV negative	5
Phenotyped units for patients with sickle cell disease	2
Blood warmer for cold agglutinin patient	1
Total	**74**

Table 16
Location of the patient for whom irradiated components were indicated but not provided

Location	No. of clinical cases
Haematology ward	41
Renal transplant unit	3
Admitted to a second hospital with another medical problem	7
Transfer to a second hospital post SCT	5
First transfusion, which should have triggered special requirements, given in a non-haematological ward in the same hospital	1
Not stated	2
Total	**59**

Of the 59 clinical-based omissions for irradiated components, the indications for irradiation were as follows:

- 29 fludarabine or other purine analogue
- 12 Hodgkin's disease
- 9 SCT
- 1 intrauterine transfusion (IUT)
- 1 Campath
- 1 lymphoma (unspecified)
- 1 immunodeficiency
- 1 anti-thymocyte globulin (ATG)
- 4 not stated.

Case 5

Wife's knowledge overlooked by staff

A male undergoing chemotherapy for Hodgkin's disease was to receive his first transfusion. The request was made by a consultant haematologist, who failed to request irradiated components and did not supply the patient with an NHS card. When admitted to the haematology ward the following day, the wife questioned the need for irradiated components but was reassured by the nursing staff that this was not necessary.

Although it is highly unlikely that the consultant was unaware of this patient's special requirements, there was neither a request nor a prescription for irradiated components. Of equal concern is the lack of knowledge of the nursing staff in the haematology day ward and their dismissal of the wife's enquiries.

Case 6

Patient comes to the rescue

An elderly patient receiving fludarabine for chronic lymphocytic leukaemia (CLL) had been given an NHS card indicating the requirement for irradiated components. However, when he was admitted to the day ward and was receiving his first red cell transfusion he enquired whether the unit was irradiated. Although the clinician had appreciated the need for irradiation, there was no awareness of the local procedure that required a special requirements form to be sent to the laboratory.

This is one example of a total of 8 cases where the clinicians were aware of the need for the patient to receive irradiated components but were not familiar with the local systems for informing the laboratory of the requirements.

Case 7

Correspondence from Transplant Centre in medical records

A patient was referred back to his local hospital following a stem cell transplant. The Transplant Centre had written a discharge summary, which had included the requirement for the patient to receive both irradiated and CMV negative blood components. However, this correspondence was not available in the case notes at the time of the transfusion and was only passed on to the team from medical records several days later.

The Transplant Centre had clearly communicated this patient's special requirements but for local administrative reasons the letter had not found its way to the correct clinical team. However, this case shows a lack of understanding by the clinicians in the receiving hospital of the requirements of patients following a stem cell transplant. No attempt had been made by the receiving medical team to contact the Transplant Centre for instructions on the patient's further management.

Case 8

General medical clinicians unaware of the requirement for irradiated blood for a patient with a past history of Hodgkin's disease

A patient was admitted with an Hb of 7.0 g/dL and a possible myocardial infarct. The admitting doctor noted the past history of Hodgkin's disease but was not aware of the requirements for irradiated blood. The patient received 2 units of red cells. The patient then elected to be transferred to the local private hospital under the same consultant where a further 2 units of non-irradiated red cells were given. When the notes were reviewed by the consultant, he noted the patient's past history and contacted the local haematologist to confirm his suspicions that irradiated blood components were required.

Although the junior medical staff had been aware of this patient's past history of Hodgkin's disease they were not familiar with the criteria for irradiated components.

Case 9

Patient on fludarabine receives non-irradiated red cells despite pharmacy protocol

A hospital transfusion laboratory receives a monthly report from the pharmacy of the patients who have been prescribed fludarabine. However, a locum haematologist prescribed fludarabine in the middle of the month and failed to give the patient an alert card or annotate the patient's case notes or inform the laboratory. Later that month the patient was transfused with 2 units of non-irradiated red cells, prior to the laboratory being aware through the monthly pharmacy report of the requirement.

Many hospitals have systems in place to try to combat communication breakdown. Although these systems provide supportive and confirmatory information, the ultimate responsibility for the prescription of specialist components rests with the clinician, and the clinical team has the responsibility of informing the laboratory.

There were 5 cases in which there was a failure to request both irradiated and CMV negative components. The indications were as follows:

- 2 post-SCT
- 1 post renal transplant on Campath
- 1 immunodeficiency
- 1 not stated.

In many instances there was a lack of knowledge on the part of the junior doctor prescribing and requesting blood for the patient, but in others the procedure for transmitting this requirement to the laboratory was neither sufficiently robust nor understood by all parties. Examples of failures are given below:

- 8 instances where the components had been prescribed but the prescriber was unaware of the system for communicating this request to the laboratory.
- 5 instances where the requester knew of the need to complete a special requirements form but in 1 case this was filed in the notes, in another there was confusion among the junior doctors as to who had completed the form and in the others the information on this form was not updated.
- In 1 instance the SCT coordinator had failed to update the system and the laboratory was not informed.
- In 1 instance there was a complete breakdown of the system in that the oncology database manager who was responsible for updating the system and informing the hospital transfusion laboratory had left the organisation and there was no replacement either for this post or a consideration of an alternative system.
- On 1 occasion the special requirements process had been changed and not all relevant staff members knew of the changes to the procedure.
- In 4 instances the diagnosis on the request form provided to the laboratory might have been recognised by biomedical scientists (BMS) to indicate special requirements, but this is not the primary responsibility of the laboratory.
- In 2 instances the patient produced an irradiation card after the transfusion was started.

Omissions to request CMV negative components:

- 2 pregnancy
- 2 HIV positive
- 1 pre SCT
- 1 acute lymphoblastic leukaemia (ALL)
- 1 neonate.

There were 2 cases of failure to supply phenotyped units for patients with sickle cell disease. In both there was a failure of communication between the clinical team and the laboratory and in 1 case staff used access to a remote issue fridge for the transfused units.

COMMENTARY on SRNM clinical cases

The request for irradiated components continues to be the single most commonly omitted special requirement. With few exceptions in 2010, the patients who required irradiated components but did not receive them either have been or continue to be under the care of a haematologist, and yet the reports this year demonstrate a lack of knowledge among all grades of members of haematology staff either of the indications for irradiated components or the means of reliably informing the laboratory of this requirement. Consequently it is essential that all members of a haematology clinical team are fully aware of the indications for prescribing these components.[3] Furthermore there is a need for a robust procedure that is owned by both the laboratory and the haematology clinical team, and that specifies the process for requesting such components. This document should clearly indicate the responsibilities of both parties. Although it may be prudent in transplant units for a given individual or coordinator to specifically undertake this role, the process should still be documented and alternative staff members trained for the role.

In a number of cases this year the failure to prescribe blood components with special requirements was identified by the nursing staff during the administration of the blood, which in some cases revealed that patients had previously received components of the incorrect specification over a protracted period of time.

Learning points

- All haematology units must devise specific educational programmes for all their staff members providing the rationale and indications for specialist components and this information should be accessible at the time of making the requests for blood components.
- All haematology units must possess a documented procedure for communicating the need for specialist components to the laboratory, including the responsibilities of both parties.
- With respect to purine analogues, systems can be developed with the pharmacy to alert either the prescriber or the transfusion laboratory of the need for irradiated components. Nevertheless, the primary responsibility for prescribing specialist components rests with the clinician and the responsibility for informing the transfusion laboratory rests with the clinical team.
- All members of the clinical haematology team should be empowered to challenge an inappropriate prescription.
- All transfusion request forms should be fully completed with as much information as possible, including relevant medical history, any known special requirements, antibodies, pregnancy, IUT and exchange transfusion (ET).

IBCT EVENTS ORIGINATING IN THE HOSPITAL TRANSFUSION LABORATORY *n* = 107

2010 has seen a total of 107 IBCT cases in which the primary error occurred in the laboratory, which represents 54% of the total 200 IBCT cases. This constitutes a 28% (*n* = 107) decrease in laboratory-related errors in 2010 compared with 2009. This decrease in the number of errors reported could be due to a number of factors: following the BSQR 2005,[4] many laboratories probably have a much more robust quality management system and are better at identifying the root cause of errors and are therefore determining more appropriate corrective and preventative action (CAPA). Feedback from inspections, from SHOT reports and other routes of sharing good practice, for example via RTCs, is probably also helping towards error reduction. Recommendations from the UKTLC[5,6] in the areas of staffing, technology and training and competence may be starting to have an impact on transfusion laboratories.

All IBCT cases are summarised in Table 10 on page 20. However, the cases whereby the primary error occurred in the laboratory are discussed in more detail below. Laboratory errors resulting in SRNM (37 cases) are discussed towards the end of this chapter.

Table 17
Summary of laboratory-related errors *n* = 107

Type of error	No. of cases in 2009	No. of cases in 2010
Wrong blood	**21**	**21**
Wrong sample selected	2	2
ABO grouping error	5	2
D grouping error	4	4
Incorrect component selected	9	11
Incorrect labelling	1	2
Wrong group selected for SCT patient	**13**	**15**
Wrong ABO group selected	7	9
Wrong D group selected	2	2
Procedural errors	4	4
Other pre-transfusion testing errors	**48**	**34**
Testing errors	9	8
Procedural errors	39	26
SRNM	**67**	**37**
Due to failure to consult patient records thoroughly	40	18
Due to poor serological knowledge/failure to recognise the special needs of a specific patient group	27	19
Total	**149**	**107**
Anti-D-related laboratory errors	**38**	**45**
Handling- and storage-related laboratory errors	**43**	**53**
Grand total laboratory errors	**230**	**205**

Mortality
There were no transfusion-related cases of mortality reported.

Morbidity
There were 5 women of childbearing potential transfused with K positive red cells this year and 1 of these had produced anti-K at the time the cases were reported. In view of the unknown K status of the remaining cases the potential for major morbidity is unknown.

In another case an 85-year-old patient experienced a DHTR as blood was electronically issued without an antibody panel, following a positive antibody screen. An anti-Jka was identified. The patient recovered.

ABO- and D-incompatibility
There was 1 ABO-incompatible red cell transfusion reported this year, following an ABO grouping error. Group AB red cells were transfused to a group A patient (see Case 10 below). In 2 cases RhD positive red cells were transfused incorrectly following D typing errors.

Wrong blood incidents originating in the laboratory *n* = 21

This year 19% (21/107) of laboratory errors accounted for wrong blood incidents. This compares to 14% (21/149) last year.

Seven cases involved paediatric patients: 3 neonates, a 3-month-old and 3 aged 2–8 years. All other cases were in adults over 18 years of age. Table 18 illustrates the time and circumstances under which these wrong blood incidents took place.

Table 18
Summary representing when wrong blood incidents occurred and their urgency

	Out of hours	In core hours	Unknown
Emergency	2	2	2
Routine	2	5	5
Unknown	1	0	2

Unfortunately, there are a number of unknowns in the above table. From the information given, approximately equal numbers of errors occurred in and out of core hours. This suggests that the error rate out of hours is greater than that in core hours, as less work is performed out of hours. However, the difference is less marked than in previous years.

The 21 errors fell into the following five categories.

Wrong sample selected

There were 2 cases where the wrong sample was used. In 1 case the incorrect sample was retrieved from a storage rack and used to crossmatch 2 units, out of routine hours. Both patients happened to be group A with no antibodies. In the second case a BMS aborted a run on the analyser due to an emergency situation but took the incorrect sample off the analyser to group manually. The sample grouped was A and the patient B but, fortunately, only FFP was required and the group B patient received group A high-titre negative FFP.

ABO grouping errors

There were 2 ABO grouping errors. One case occurred during core hours while performing routine manual grouping. Manual results were written on a worksheet and the conclusion documented. One BMS documented the group incorrectly, a second BMS failed to notice the error and a third BMS who entered the result onto the computer also failed to notice the error. The O RhD positive 21-year-old male was assigned the group A RhD positive. Fortuitously only platelets were required and group A platelets were transfused. The reporter stated that automation was to be purchased for the laboratory in the next couple of months. The error was discovered on receipt of a subsequent sample. The second case is Case 10 below.

A further ABO grouping error is noted in Chapter 10 (page 63). An AB RhD negative cord group was misinterpreted as A RhD positive and manually entered on to the LIMS, resulting in an unnecessary 1500 iu dose of anti-D Ig being given to the mother. It is interesting that this case was reported as an anti-D error rather than an ABO typing error.

A further 9 grouping errors are reported in Chapter 21 on near misses (page 128). All of these occurred while using manual grouping techniques.

Case 10

Manual grouping error

A sample was grouped as AB RhD positive using a manual technique. Two units were requested and 2 units of AB RhD positive red cells crossmatched. One of the units was incompatible. A third unit was crossmatched and found compatible and the 2 compatible units were issued and transfused uneventfully. The sample was put on the laboratory analyser for confirmatory testing but a grouping interpretation could not be made. A sample was sent to NHS Blood and Transplant (NHSBT) to investigate the reason for the positive reaction with the incompatible unit. NHSBT found that the patient was A RhD positive but had a very weak anti-B. The reporting hospital thought there must have been 'splash' between reagents in the manual group to have given the erroneous result with the reagent anti-B in the original forward group.

D grouping errors

There were 4 errors in D typing. Three of the errors appear to have been misreading/transcription errors when performing manual groups, while the fourth case involved an inappropriate action by a BMS following an unspecified warning on a blood grouping analyser. Two cases, neither of which involved women of childbearing potential, resulted in RhD positive blood being given to RhD negative patients, 1 of which resulted in the patient developing anti-D. In the other 2 cases, despite being mistyped as RhD positive, RhD negative units of blood were selected and transfused.

Further D typing errors have been identified from the chapter on anti-D errors (Chapter 10, page 63):

- A cord group was manually transcribed incorrectly on to the LIMS as RhD positive, leading to an unnecessary 1500 iu dose of anti-D Ig being given.
- A grouping result of A RhD positive was manually entered onto the LIMS incorrectly as A RhD negative and the woman was then given 1250 iu of anti-D Ig unnecessarily.
- A maternal group was incorrectly transcribed and authorised on the LIMS as RhD positive so anti-D Ig was not given.
- A cord D type of RhD positive was uploaded to the maternal record on the LIMS. The mother was RhD negative but did not receive anti-D Ig.

There were 3 further cases involving weak RhD types, which show poor practice. In 1 case a 10-year-old historic group, confirmed by a manual tube group, was used to issue anti-D Ig when the routine group indicated a weak D positive result. In the second case the patient was known to have a weak D antigen but a manual tube group gave a result of RhD negative and anti-D Ig was issued on the basis of this result. In the final case two technologies gave different results, 1 D negative and 1 D positive (weak). Anti-D Ig was issued but the reference laboratory later confirmed that the patient was weak D positive (see Chapter 10, page 63). However, where there is doubt about the D type of the mother, the safest policy is to issue anti-D Ig.

Learning point

- Variations in D typing of patients with a weak D antigen may be unavoidable as technologies differ in their sensitivity but it is important that the D type is determined by the most robust routine method available.

Incorrect component selected

In 11 cases an incorrect component was selected. Five of these involved platelets. Four cases resulted in RhD positive platelets being given to RhD negative patients, 3 of whom were paediatric patients (1, 2 and 7 years of age; 1 male, 2 females) and the fourth was a 47-year-old female patient. In the fifth case a porter requested the collection of platelets for a specific patient, but the BMS handed over platelets that were intended for another patient.

Four cases involved red blood cells (RBCs). In 2 cases RhD positive red cells were issued when RhD negative red cells were required; both patients were male. In 1 neonatal transfusion, group A red cells were selected, matching the baby's group, when, according to local policy, group O red cells should have been used as the mother was group O. This was a deviation from local policy and it was not stated whether an indirect antiglobulin test (IAT) crossmatch was performed. In another neonatal transfusion the BMS requested six paedipaks for an ET, not knowing that a single unit of the

specialist component red cells for ET should have been requested and not understanding the difference in specification of these two different red cell components.

Two cases involved plasma components, 1 in which a B RhD negative patient was transfused with group O cryoprecipitate when group A was available, and a second involving the transfusion of cryoprecipitate when FFP was requested.

Incorrect labelling

Only 2 cases were received as a result of incorrect labelling, both of which involved labels being transposed. One case resulted in an incompatible unit being labelled compatible and subsequently transfused. The other resulted in a patient receiving blood that was not crossmatched for them. No adverse reactions were reported. It is significant that a further 34 cases involving mislabelling components were reported as near misses and a further 27 cases as RBRP (see Chapter 7.2, page 46).

COMMENTARY on laboratory wrong blood incidents

The number of laboratory errors contributing to wrong blood events has remained constant. This year errors in component selection mainly involved mis-selection of RhD positive components for RhD negative individuals, against local policies.

It is interesting this year that an ABO error and a number of D typing errors have been reported through the adverse events relating to the anti-D Ig route when the root cause of the anti-D error has been a grouping error. This means that the detail of the grouping error is not available for analysis.

It appears that a number of manual groups are performed on maternal samples in order to issue anti-D Ig, which is hard to understand given that there is a 72-hour window from the time of the sensitising event for anti-D Ig to be issued and transfused. Routine grouping methods would appear to be more appropriate.

Another interesting issue that has come to light this year, following the complete analysis of the near miss data, is that looking at the number of actual SHOT cases in a category does not always reveal the extent of a particular problem. Although there are only 2 cases of incorrect labelling of components that have resulted in IBCT cases, there have been 61 cases of incorrect labelling reported to SHOT. This is an area of laboratory practice that should be looked into.

Table 19
Trends in laboratory-based ABO grouping errors, with causes

Year	ABO errors	Wrong sample tested	Interpretation/ transcription errors	Other	ABO-incompatible red cell transfusions	Sequelae
2010	3	1	1	1	1	No morbidity
2009	7	2	5	0	2	1 AHTR
2008	8	3	5	0	4	1 AHTR
2007	7	3	4	0	1	No morbidity
2006	6	2	3	1	0	No morbidity
2005	22	9	12	1	3	1 AHTR
2004	18	5	12	1	6	1 death 1 major morbidity
2003	17	8	9	0	6	2 major morbidity

AHTR, acute haemolytic transfusion reaction.

The trend shows a decrease in the number of reports over time, despite an overall increase in reporting to SHOT. This is a positive finding and may be seen as a sign of improvement.

Table 20
Trends in laboratory-based D grouping errors, with causes

Year	D errors	D errors from anti-D chapter	Wrong sample tested	Interpretation/ transcription errors	Tx of D+ to D- individual	Other	Sequelae
2010	4	7 (3 weak D)	0	4	2	0	1 patient produced anti-D but was not of childbearing potential
2009	5	NK (7 weak D)	1	4	2	0	No morbidity
2008	11	NK	0	11	10	0	3 patients produced anti-D but none was of childbearing potential
2007	4	NK	1	3	3 (I x 33-year-old female)	0	No morbidity

Tx, transfusion; NK, not known.

In 9 cases it was believed that the final bedside check could/should have picked up these primary laboratory errors and prevented mistransfusion.

Learning points

- 5/6 grouping errors reported in this chapter and all grouping errors in the near miss chapter (Chapter 21) were made using manual procedures. The UKTLC recommends the use of 24/7 automation for ABO/D grouping.[5,6]
- D grouping errors resulted in the erroneous administration of anti-D Ig and were reported according to that outcome. Reporters are reminded that if the primary error was in the determination of the D group, then the case should be reported as a grouping error (IBCT).

Wrong ABO- or D-type blood components issued for SCT/BMT recipients *n* = 15

All cases were routine transfusions, 1 case involved a 4-year-old patient and the remainder were in adults. Seven of the cases occurred during normal working hours, 4 were outside normal working hours and 4 were unknown.

There were 12 cases in which BMT/SCT patients received a component of an unsuitable ABO group, 8 red cell and 4 platelet transfusions. In 7 of these cases group A red cells were transfused to group A patients who were recipients of group O BMT/SCT and therefore should have received group O red cells. RhD positive red cells were given in error in 2 cases following incorrect component selection.

In 1 case the correct red cells were selected but were then electronically issued when a full serological crossmatch should have been performed. In most cases the error occurred when the BMS issuing the component failed to heed appropriate warning flags/comments on the patient notepad on the LIMS. However, in 1 case the instruction on the LIMS was incorrect; in 1 case there were two LIMS in operation on two hospital sites and the flag was on only one system and that system was not checked; and in another case an NHSBT red cell immunohaematology (RCI) department crossmatched the blood but was not informed by the referring hospital that the patient had undergone an allo BMT and therefore needed blood of the donor group.

Other pre-transfusion errors *n* = 34

The number of cases in this category has fallen from 48 cases last year. Eight cases involved paediatric patients: 1 neonate, 3 who were ≤5 months, 2 who were 1 year of age, a 10-year-old and a 14-year-old. Table 21 illustrates the time and circumstances under which these pre-transfusion errors took place.

Table 21
Summary representing when pre-transfusion incidents occurred

	Out of hours	In core hours	Unknown
Emergency	7	1	1
Routine	4	14	2
Unknown	1	3	1

The staff involved out of hours included 1 BMS who normally works in transfusion, 1 who does not routinely work in transfusion and 11 cases where the status of the BMS was not known. It would be helpful if this information was complete on reports submitted to SHOT so that a fuller picture of staff groups involved in making errors could be obtained.

The 34 errors have been divided into:

- testing errors, i.e. the correct tests were performed but incorrect results obtained because of poor performance of the test, transcription error or incorrect interpretation
- procedural errors, e.g. incorrect test selection or failure to follow procedure.

Testing errors *n* = 8

Eight errors occurred during pre-transfusion testing:

- Crossmatch results were entered into the LIMS and blood was issued before the crossmatch was read. When the crossmatch was read 1 of the units was incompatible.
- Antibody screen and crossmatch results were entered into the LIMS and blood was issued before either test was read.
- A contaminated tube led to a false positive antibody screen and an erroneous antibody identification of auto anti-D and the unnecessary use of RhD negative red cells.
- During a crossmatch an analyser gave an error code of 'wrong liquid level'. The wells were manually edited and reported as compatible. In fact insufficient plasma had been added to the crossmatch wells for both units, i.e. units were issued without a full crossmatch being performed.
- Four interpretation errors occurred during antibody identification, all leading to red cells, positive for the antigen to the correct antibody, being transfused. One of these cases involved an erroneous interim report to a hospital laboratory from an NHSBT RCI laboratory. No reactions were reported.

Procedural errors *n* = 26

There were many different types of procedural errors.

Testing unsuitable samples *n* = 7

There were 7 cases where an inappropriate sample was used to issue blood:

- In 1 case a transfusion at another site complicated the sample timing calculation.
- In a second case transfusion of an emergency O RhD negative unit had complicated the sample timing calculation.
- In another case the complete transfusion record was not found due to different numbers being used as the primary identifier. This led to the wrong sample being used for crossmatch.

- In another case a pre-transfusion reaction sample was used to issue further units of blood when a post-reaction sample was available.
- In 1 case a new sample was not requested for a baby who was now 5 months old and a unit was electronically issued.
- In 1 case a unit was re-issued in error and transfused >72 hours after transfusion of a previous unit.
- In the final case a BMS failed to test a fresh sample sent to the laboratory and issued blood using a sample that was >72 hours old. The patient had received 4 units of blood issued using the original sample.

Failure to find historic records *n* = 3

Of the 3 cases, historic records were not found by the laboratory for the following reasons:

- In 2 cases patients were registered under two numbers and the laboratory's patient search strategy failed.
- In 1 case the BMS failed to search a legacy database, which is against laboratory protocol.
- All 3 patients had clinically significant red cell antibodies on file that were no longer detectable. No reactions were reported.

Cases in which blood was issued with incomplete pre-transfusion testing or failure to follow correct procedure *n* = 10

- In 2 cases appropriate action was not taken to update patient computer records based on the patient history.
- In 3 cases blood was issued without an antibody panel, following a positive antibody screen. One of these cases resulted in a DHTR due to anti-Jk^{a}.
- In 1 case blood was transfused to a 15-month-old without an antibody screen being performed. The patient was treated as a neonate.
- In 1 case a 14-year-old was transfused 2 units of RBCs before the G&S results had been authorised.
- In 1 case an O RhD negative paedipak unit was issued to a 19-week-old baby without a group and antibody screen being performed.
- In 1 case a female patient of childbearing potential with sickle cell disease was given blood that was not RhD phenotype matched. An RhD phenotype had been requested on the LIMS but was not performed over the weekend. The patient formed anti-C.
- In 1 case a haemolytic transfusion reaction was caused by a missed anti-Jk^{a} in the pre-transfusion sample (see Case 11).

Case 11

Antibody identification must be current

A patient was crossmatched for a 2 unit transfusion. Both crossmatches were negative; the patient was previously known to have an anti-E and a weak auto-antibody. The antibody screen results agreed with previous findings and an antibody identification panel was not performed despite the patient having been transfused since the last antibody identification. While the first unit was being transfused the patient became hypotensive, was sweating and shaking, had loin pain and was breathless. A transfusion reaction investigation revealed an anti-E plus anti-Jk^{a} in both the pre and post transfusion samples. The transfused unit was Jk(a+b+).

Errors during crossmatching *n* = 5

There were 5 cases in which blood was electronically issued inappropriately:

- 2 cases involved babies where an EI was performed when maternal antibodies had been detected.
- In 1 case, despite anti-E being clearly flagged on the patient's record, blood was issued by EI.
- In 1 case EI was performed erroneously because the patient record was wrongly updated to state that the patient was suitable for EI when a report from NHSBT RCI actually stated that blood should be crossmatched by an IAT method.
- In the final case EI was used inappropriately following a manual edit of a result from an automated analyser. The problem was that the edit had been made on the LIMS and no record of the edit made – a comment should have been added to the group and antibody screen results.

In addition, in 2 of the 3 cases in the preceding paragraph, where antibody identification was not performed prior to blood issue, blood was issued by EI.

An additional procedural error was due to a communication failure between NHSBT and a hospital laboratory. A fax was sent by NHSBT to recall a unit of blood, the fax got jammed and the message was not followed up by a phone call in accordance with the procedure. This resulted in the unit being issued and transfused when this could have been prevented.

NHSBT-related errors are collated towards the end of this chapter for clarity. There are also a number of pre-transfusion testing errors reported in the near miss chapter (Chapter 21, page 128):

Table 22
Examples of pre-transfusion testing errors reported as near misses

Category	No. of errors
Sample booked in under incorrect record	9
Incorrect patient identifiers entered into LIMS	27
Incorrect patient merges on LIMS	2
Incorrect sample used for grouping	2
Incorrect sample used for crossmatching	4
Invalid sample used in crossmatching for a frequently transfused patient	9
Incomplete testing prior to issue	7
Inappropriate editing of results from analyser	4
Expired antibody identification panel in use	4

COMMENTARY on pre-transfusion testing

Pre-transfusion testing errors have decreased from 21% (48/230) in 2009 to 16% (34/205) in 2010. Errors in pre-transfusion testing mirror those of previous years: incomplete testing, inappropriate actions following alerts and misinterpretation during antibody identification. To echo the advice given by UK NEQAS BTLP, 'when interpreting antibody identification results all available information should be reviewed including patient phenotype, differential reaction by technique and results of all cells tested including screening cells. Interpretation and documentation of antibody identification results is an error prone manual process and this should be considered when establishing procedures for reporting antibody identification'.

The procedural errors also mirror those of previous years, including failure to find patients' historical records. This problem is discussed further in the chapter on errors relating to IT (see Chapter 7.1). Use of unsuitable samples for crossmatch and incomplete testing remain issues and laboratories should look critically at their LIMS and assess whether all computer algorithms and alerts that can be applied are being used as effectively as possible, e.g. alerts when samples are unsuitable in terms of timing, alerts when tests are incomplete and reflex testing such as automatic requesting of an antibody identification test when a positive antibody screen is obtained. These alerts should be used as reminders for staff and do not replace thorough training and competency-based assessment, which must include appropriate actions on receipt of alerts/warnings whether these are on the LIMS or an analyser.

All laboratories should have implemented the requirements of the Medicines and Healthcare products Regulatory Agency (MHRA) Guidance on Electronic Issue (May 2010) by March 2011.[7] Properly implemented use of this guidance would have prevented 4 of the cases reported above.

Learning points

- Laboratories need to look critically at the way in which mother and baby records are linked and assess how robust this linkage is.
- Laboratories should critically assess the use of alerts/warning/algorithms on the LIMS and ensure they are being used as effectively as possible. The ability to easily override warnings/alerts should be discouraged.
- Training and competency-based assessment must include appropriate actions on receipt of alerts/warnings, whether these are on the LIMS or an analyser.
- Training and competency-based assessment must include, and indeed highlight, the less common transfusion scenarios and standard operating procedures (SOPs) must give clear instructions on the use of infrequently used components.

LABORATORY-BASED CASES OF SRNM *n* = 37

There has been a big reduction in the number of cases reported, 37 compared to 67 cases last year. Due to the smaller number of cases reported it has been possible to analyse these cases more fully.

Eleven cases (11/37 or 29.7%) involved paediatric patients and in 6 of these cases the special requirement missed was age related: 5 cases where MB-treated FFP/cryoprecipitate should have been issued to patients under 16 years of age but was not and 1 case where a child under 1 year old was issued with red cells that were not CMV negative.

The 37 SRNM errors have been divided into SRNM due to:

- poor serological knowledge/failure to recognise the special needs of a specific patient group
- failure to consult patient records thoroughly.

SRNM due to poor serological knowledge/failure to recognise the special needs of a specific patient group *n* =19

Failure due to poor serological knowledge/carelessness in selection *n* = 3

- 1 case involved a 39-year-old female who was known to be R_2R_2 (cDE/cDE) and have anti-C. She was transfused RhD negative RBCs and developed anti-E as a result.
- 1 case in which a BMS ignored a warning flag stating the need for E- and C- units to be selected for a patient with sickle cell disease. Red cells that were not phenotypically matched were issued and anti-E was detected 18 days later.
- In the final case the BMS misunderstood the requirements for a 91-year-old patient with autoantibodies, and rather than issuing units identical to the patient's own Rh phenotype, i.e. E- and K-, issued e- and K- units, resulting in the patient receiving 1 E+ unit.

There was 1 additional case in which the BMS failed to update the special requirements on the patient notes and did not communicate the need for using a blood warmer to clinical staff (see communication errors, towards the end of the chapter, page 40).

Failure to recognise the needs of specific patient groups *n* = 15

There were 6 cases in which K+ units were issued against national recommendations and/or local protocol:

- In 4 cases K+ units were issued to women of childbearing potential. All cases were emergencies involving acute blood loss. In 3 cases no LIMS alerts, based on gender and age, were present. In 1 case an alert was missed.
- In 1 case the local protocol dictated that all blood issued as group specific should be K- and K- units were not issued. The patient receiving the group-specific unit was found to have an anti-K when pre-transfusion testing was completed.
- In 1 case the local protocol dictated that all flying squad units should be K-. One unit was not and was transfused to a woman of childbearing potential.

There were 5 cases involving 9 patients of failure to supply MB-treated FFP or MB-treated cryoprecipitate to children under 16 years of age. In only 1 of these cases was a warning flag missed. In the other cases the LIMS did not appear to have warning flags set up, based on age of patient, which may have alerted staff to the incorrect component selection. Neither was addition of a warning flag mentioned as a corrective action in any of the cases.

There were 3 reports involving 4 patients where pregnant women were not issued CMV negative units.

There was 1 case which involved a patient under 1 year old receiving components that were not CMV negative.

Table 23
SRNM due to failure to consult patient records thoroughly *n* = 18

Failure	No. of cases 2009	No. of cases 2010
Failure to provide irradiated components ■ Missed tick on request form ■ Missed flags ■ Clerical error ■ Flag required irradiated, CMV negative issued ■ NHSBT failed to irradiate buffy coats, not detected in the laboratory	22	**9** 2 4 1 1 1
Failure to provide CMV negative components ■ Missed tick on request form ■ Flag input error	10	**4** 3 1
Failure to provide CMV negative and irradiated components ■ Missed tick on request form ■ Failed to order correct special requirements on BTS order form and error not detected at issue	4	**3** 2 1
Failure to provide human leucocyte antigen (HLA) matched platelets ■ Missed flag – BMS busy	4	1
Failure to provide human platelet antigen (HPA) matched platelets ■ Flag input error as a result of inadequate handover	0	1
Total	**40**	**18**

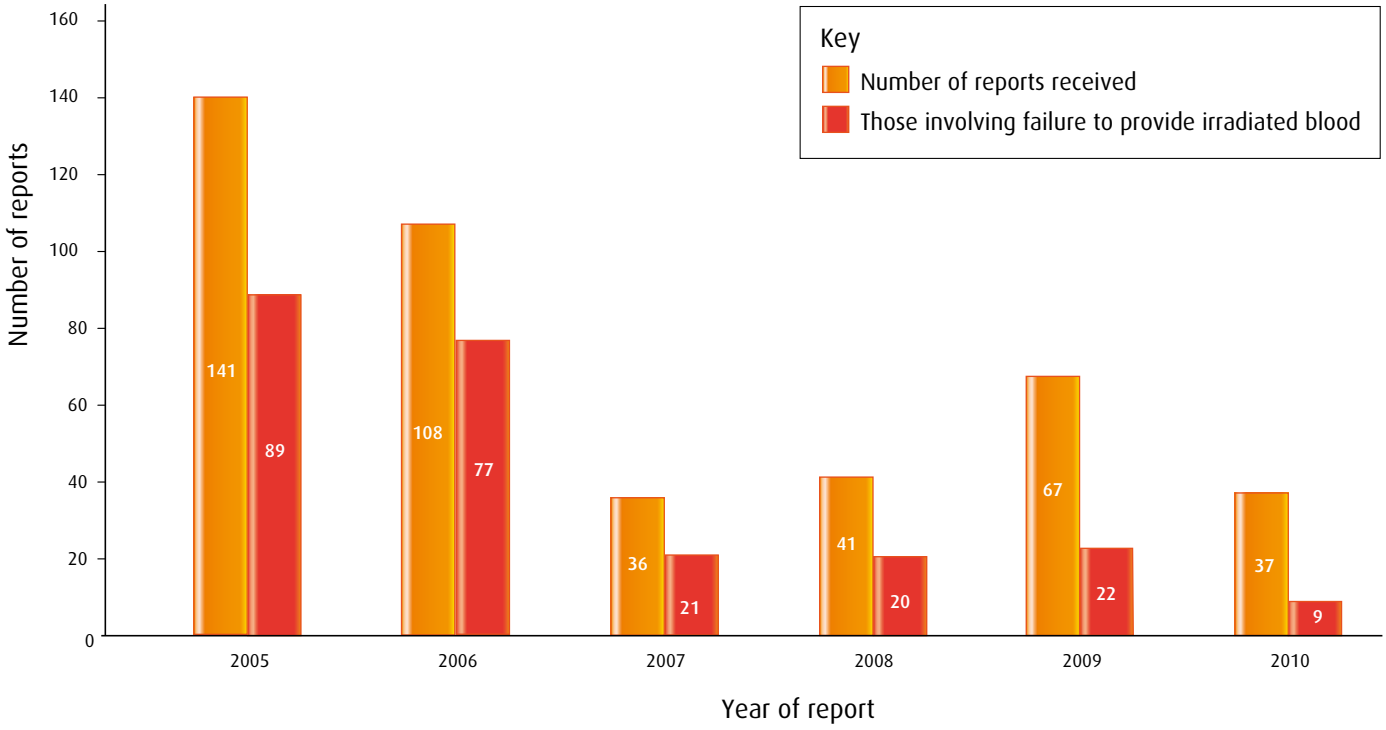
COMMENTARY on SRNM laboratory cases

In a climate of increased reporting there has been a significant reduction in the number of laboratory-based SRNM cases this year, which is very encouraging. There could be a number of factors involved in this improvement, for example the effects of the BSQR 2005[4] and the ethos of good manufacturing practice with improvements in root cause analysis and CAPA following errors and or audits. It will be interesting to see whether this reduction in SRNM cases can be sustained or improved upon further.

There were still 11 cases where warning flags were missed/misinterpreted, 9 cases where warning flags were not in place and could have alerted BMS staff to a special requirement, and 2 cases where flags were entered incorrectly on to the LIMS. Consequently there are still occasions when appropriate, robust warning flags/alerts do not appear to be in place, for example a warning based on age and gender for the issue of K- red cells and a warning based on age for the issue of MB-treated FFP. Whether this is due to the deficiencies of the LIMS or failure of the hospital to configure the LIMS appropriately is not always clear. However, errors do also continue to occur when warning flags/alerts on the LIMS are missed by BMS staff. Whether these are due to poor alerts, lack of training or simple oversight again is not always clear.

There were 7 cases where the tick box on the request form indicating the need for a special requirement was missed. Hospitals must risk assess the process in place for communicating special requirements and ensure that it is as robust as possible. A number of ways of pre-alerting transfusion laboratories to special requirements are in use, for example notification from the pharmacy on receipt of a prescription for a purine analogue or notification from the haematology department when a purine analogue is prescribed. Different processes work best in different places and the simplest, most robust system for the particular environment must be selected. Of course, pre-alerting the laboratory is only a good idea if the LIMS has robust alert mechanisms.

Figure 5
Laboratory-based cases of SRNM 2005–10



Learning points

- Critically assess the use of alerts/warning/algorithms on the LIMS and ensure they are being used as effectively as possible.
- Risk assess the process in place for alerting the laboratory to the need for special requirements and ascertain if that method is as robust as possible.

Errors involving NHSBT *n* = 4

There were 4 cases in which NHSBT was involved. These are discussed in the text but grouped here for clarity:

- There was 1 case in which a recall was initiated by NHSBT and a fax sent to the appropriate laboratory; however, unknown to NHSBT, the fax got jammed and the message of a recall was not followed up with a phone call or another form of communication, which resulted in the recalled unit being transfused.
- In 1 case incorrect information was passed onto the laboratory following antibody identification. NHSBT reported that anti-Le^{a} and Le^{b} were detected but it was only 2 days later that the laboratory received a phone call from NHSBT informing them that there was a mistake in the antibody identification and that the antibodies detected were anti-M and anti-S. Unfortunately, incorrectly phenotyped blood had already been transfused to the patient.
- In 1 case buffy coats were not irradiated.
- In 1 case issue of non-MB-cryoprecipitate when MB-cryoprecipitate was requested. This was not noticed by the laboratory.

Errors involving miscommunication *n* = 4

There were 4 cases where failures in communication between staff resulted in an error; these are all reported in more detail throughout the chapter but have been grouped here for further emphasis:

- In 1 case the blood transfusion laboratory did not communicate to clinical staff the need for the use of a blood warmer.
- In 2 cases NHSBT did not communicate effectively with the hospital laboratory: 1 case involved the recall of a unit and the other involved erroneous antibody identification results.
- In the final case the hospital laboratory failed to inform the NHSBT RCI laboratory that the patient had recently received a BMT.

Recommendations

Recommendations for clinical IBCT cases

See the Key Messages and Main Recommendations in Chapter 6 on page 15.

Recommendations for laboratory IBCT cases

- Robust communication procedures are required both within the laboratory and to cover the laboratory/clinical interface.

  Action: Transfusion laboratories, HTTs, hospital transfusion committees (HTCs)

- Easily interpreted flowcharts should be considered to clarify existing policies and procedures.

  Action: Transfusion laboratories, HTTs, HTCs

- Successive SHOT reports have demonstrated that the majority of ABO/D grouping errors are incurred with manual procedures. The UKTLC has therefore recommended the use of 24/7 automation. In the event that resources cannot be made in the short term to fund this development, a risk assessment must be conducted with clear mitigation strategies.

  Action: Transfusion laboratories, pathology managers, clinical risk committees

For active recommendations and an update on their progress, please refer to the SHOT website.

7.1. Errors Relating to IT Systems (IBCT IT)

In 2010, there were 56 reported incidents of errors relating to IT systems (see Table 24), compared with 59 in 2009 and 44 in 2008. Fifty-four of these incidents originated in the transfusion laboratory. A total of 43 cases involved red cells, 8 involved platelet components and 5 involved plasma components. Five of the 56 cases occurred in children, 7 of whom were infants below the age of 1 year. This year, 10 errors relating to the administration of prophylactic anti-D Ig were reported (see Table 25) and these are discussed later in this chapter.

Table 24
Categories of IT systems errors

Error	Reports	Non-irradiated component transfused	Antigen-positive unit transfused	Non-CMV-negative unit transfused	Wrong group after SCT	EI error	Other
Failure to consult or identify historical record	4	0	2	0	1	1	
Ignored/missed warning flag	22	3	5	0	11	1	1 (failed to issue MB-FFP to a child)
Failure to update warning flags	12	3	3	5	1	1	1 (irradiated RBC unit issued after expiry)
Computer system down	0	0	0	0	0	0	
Data not transferred from old system	1	1	0	0	0	0	
Electronic blood tracking system errors/misuse	1	0	0	0	0	0	1 (RBC unit transfused after >30 minutes out of controlled storage)
Failure to merge or reconcile records	4	2	1	0	1	0	
Error/deficiency in computer system or misuse	12	0	1	1	0	2	7 (miscellaneous – see text)
Total	**56**	**9**	**12**	**6**	**14**	**5**	**10**

Case 1

Failure to check historical record leads to issue of non-HLA-matched platelets

A patient with severe aplastic anaemia was refractory to random donor platelets because of HLA-alloimmunisation. A non-urgent request for further platelets was made in normal working hours but the transfusion scientist did not check the historical record on LIMS and unselected platelets were issued.

Case 2

Failure to transfer warning flag to current database leads to delay of stem cell harvest

A patient with acute leukaemia in remission was transfused with non-irradiated platelets 5 days before a planned autologous stem cell harvest. Local policy is to administer irradiated components from 14 days before stem cell harvest. Special requirements data had not been successfully transferred to the new LIMS database. The harvest was delayed but there were no clinical sequelae.

Case 3

Separate LIMS on two sites in same hospital group leads to transfusion of inappropriate blood group after allogeneic stem cell transplant

A group B RhD positive patient with relapsed acute myeloid leukaemia (AML) received an allogeneic transplant from a group O RhD positive donor. Protocol specifies issue of O RhD positive components after transplant. Warning flags were placed on LIMS in site 1, but patient treated on site 2. Following request for platelets, only the site 2 database (with details of his original group) was searched, contrary to the laboratory SOP, and B RhD positive platelets were issued on two consecutive occasions. The patient, aware of his post-transplant blood group change, drew this to the attention of clinical staff after the second occasion.

Case 4

Transcription error in laboratory leads to inappropriate EI of red cells

Patient found to have weakly positive antibody screen of uncertain specificity and referred to the reference laboratory. No definite atypical antibodies were identified, but reported as unsuitable for EI. Only the first part of the reference laboratory report ('no atypical antibodies detected') was placed on the hospital LIMS and the patient subsequently received red cell transfusion on two occasions by EI before the error was discovered. There were no adverse clinical consequences.

Case 5

Failure to update warning flag in a timely fashion and inadequate handover between shifts leads to transfusion of non-HPA-matched platelets to neonate with possible neonatal alloimmune thrombocytopenia (NAITP)

A thrombocytopenic neonate was suspected of having NAITP and HPA-1a 5b negative platelets were requested. The request arrived just before shift handover and the special requirement was not entered on the LIMS as the baby's blood group had not yet been established. The special requirement was also not recorded in the handover note pad. The BMS coming on duty thus ordered standard neonatal platelets (although the special requirement was also stated on the clinical request form). There were no adverse consequences.

Case 6

Sickle cell patient with known alloantibodies transfused with unselected red cells because of duplicate hospital number and failure to identify historical record

A patient with sickle cell disease was admitted urgently through the A&E and issued with a new hospital ID number. A crossmatch request for red cells was received by the laboratory and the historical record only checked under the new number. The patient had extensive previous records under a different registration number, with known clinically significant antibodies (not detectable on current screen). These would have been identified by a computer check under name and date of birth. Unselected red cells were issued but another BMS recognised the patient's name as the request forms were being filed. An urgent recall was undertaken and the patient received only '15 drops' of the unselected blood.

Case 7

Patient with HbSC disease given non-phenotyped units from a remote issue fridge

A patient with HbSC disease was admitted as a trauma patient and was transfused 2 units of red cells prior to the laboratory being aware of the special requirements. When further units were requested, the laboratory performed the additional testing, crossmatched suitable units and informed the haematology specialist registrar (SpR) that units were ready for collection. However, the patient was on ITU, which has access to a remote issue fridge and the patient had not been blocked from remote issue. The patient was transfused with units from this fridge that were not confirmed HbS negative nor matched for RhD and K antigens as recommended in the BCSH guidelines.

COMMENTARY

As before, failure to update warning flags on the LIMS or transfer patient data from legacy computer systems, failure to notice (or heed) warning flags and failure to consult the historical record remain common causes of IBCT. Four errors were due to failure to merge or reconcile records. Five reports (9%) involved patients under 16 years and 7 (12.5%) involved infants under 1 year.

Fifty-four of the IT-error cases reported to SHOT this year originated in the laboratory (96%). Only 12 (21%) of these occurred outside 'core' laboratory working hours and 16 (28%) in an emergency situation. The percentage of errors occurring outside normal hours is similar to the proportion of out-of-hours requests (25%) found in the audit of 'When and why is blood crossmatched'.[1] As before, the large majority of errors involved regular laboratory staff during normal working hours. A number of the reports sent to SHOT this year commented that low staffing levels, stress and absence or unavailability of senior staff members contributed to the human error in the transfusion laboratory. Although most errors were reported from the laboratory, many episodes also involved clinical errors in the process, most commonly failure to request or prescribe special requirements such as irradiated or CMV-negative components. Around 30% of the errors would have been preventable at the point of the bedside check.

A particular feature this year is the number of reported errors in the selection of blood components of the appropriate group after allogeneic haemopoietic stem cell transplantation (14 cases, the single largest clinical category). Most cases were laboratory errors caused by missing or ignoring warning notes on the LIMS but some cases also clearly showed difficulties in interpretation by laboratory and clinical staff. As noted in the 2009 SHOT report, selection of the appropriate blood group after allogeneic stem cell transplant can be complex and counter-intuitive. We re-emphasise the recommendation that a post-transplant transfusion plan be agreed and circulated for each patient. Both laboratory and clinical staff involved in this process should be appropriately trained and have relevant serological knowledge.

Three of 4 cases where there was a failure to issue imported, virucidally-inactivated FFP (MB-FFP) for patients under 16 years were attributed to a deficiency in the LIMS, specifically the inability to flag this requirement automatically on an age basis. In the fourth case, the BMS missed or ignored a warning flag.

IT errors were implicated in 5 cases of inappropriate EI of red cell components, most often due to failure to identify historical records or heed warning flags disqualifying the patient from this technique.

Anti-D Ig errors

Table 25
Errors relating to administration of prophylactic anti-D Ig

Error	Reports	Unnecessary anti-D administered	Failure to administer anti-D or excessive delay
Error when transcribing result of mother or baby's group into LIMS	4	3	1
Data not transferred from old computer system	1	1	0
Failure to consult historical record	2	2	0
Computer system down	1	0	1
Maternal group entered into baby's record on LIMS	1	0	1
Accessed wrong baby's record on LIMS	1	0	1
Total	**10**	**6**	**4**

There were 10 reports in 2010 where laboratory IT-related errors or problems led to the unnecessary administration of anti-D Ig (6 cases) or omission/delay in giving anti-D prophylaxis (4 cases). In a similar pattern to IT errors in general, 80% of these cases involved staff who routinely work in the transfusion laboratory and 70% occurred within normal working hours.

There were 4 postnatal anti-D Ig administration errors directly related to the transcription of cord blood grouping results into the LIMS. In 3 cases the tests were performed by a semi-automated technique and by a manual technique in the other case; the common feature was the requirement for human intervention in transcribing the results into the LIMS. Three of these mothers received an unnecessary postnatal anti-D Ig injection and 1 failed to receive anti-D Ig within 72 hours of delivery. Clearly, any system that requires manual transfer of test results into the laboratory computer risks transcription error. In 3 of these cases, the local laboratory procedure mandates a check by a second BMS but this was not performed.

Three mothers received unnecessary routine antenatal anti-D prophylaxis (RAADP) following a clinical request. All were due to failure to check or identify the historical record. One mother was RhD positive, a second had known immune anti-D and in the third case the mother was known to have a weak D antigen (confirmed by the reference laboratory) but the record had not been transferred to the new laboratory computer.

The other 3 errors were erroneously entering the mother's blood group (RhD negative) on the baby's LIMS record, leading to failure to administer postnatal anti-D Ig, accessing the wrong record and reporting the baby as RhD negative rather than RhD positive, leading to delay in anti-D Ig administration, and delay in booking in and testing a maternal sample after a vaginal bleed because 'the computer was down', leading to a 36-hour delay in administering anti-D Ig.

Improving laboratory standards

(based on data from 2010 and previous reporting years)

Frequent reconciliation, or linking, of multiple computer records on the same patient is important for safe practice (a clear historical trail of all amendments to the records must be maintained to comply with BSQR[2]). This should be a routine laboratory process that can be performed by appropriately trained and competency-assessed senior staff.

The problem of multiple hospital numbers and case records could be reduced by routine use of the unique NHS number as a primary patient identifier in line with the recommendation from NPSA SPN 24.[3]

When new laboratory IT systems are installed, patient data from the old system should be transferred to the new system. Wherever possible this should be done electronically to avoid transcription errors.

When laboratory IT systems are off-line, non-essential transfusions should be avoided. Robust manual back-up procedures and recovery plans must be in place and tested. Manual transcription of results should be kept to an essential minimum.

Laboratory IT systems should ensure that warning flags are prominently displayed, preferably on the opening screen. Where appropriate (e.g. criteria for electronic selection) it should not be possible to override or bypass flags. Alert systems should not prevent the issue of clinically appropriate components of a different group to the patient (such as after SCT).

Transfusion laboratories should have access to the hospital patient administration system (PAS) and the ability to review haematology results online (ideally on the same screen).

All laboratories using electronic selection to issue red cells must ensure that their SOPs are consistent with national guidelines and followed fully by all laboratory staff.[4] The computer algorithms in use must prevent issue outside the guidelines.

IT systems to support transfusion safety, monitoring and traceability outside the laboratory (e.g. blood-tracking systems and bedside ID systems) should integrate with laboratory systems and processes. Laboratory staff must understand the working of these systems and be trained and competency assessed to react appropriately to alarms and warnings, and provide support and advice to clinical areas on a 24/7 basis. All clinical staff using these systems must be trained and competency assessed. This is crucial in clinical areas, such as operating theatres and delivery suites, where rapid access to emergency blood stocks is essential.

Recommendations

- The two key recommendations made in the 2009 SHOT report (namely the need to produce a post-transplant transfusion plan for each patient and to consult the patient's historical record on LIMS; see SHOT website) remain highly pertinent, especially in the light of increased reports of mis-selection of blood components of the appropriate group after allogeneic haemopoietic SCT and continuing failures to identify or heed historical records.

- Transcription errors in entering semi-automated or manually performed cord blood grouping results into the LIMS can result in unnecessary administration or failure to administer postnatal anti-D Ig. Wherever possible, test results should be transferred electronically into the LIMS. Otherwise, there should be robust independent checking procedures in place to review and confirm manually transcribed data.

  Action: Lead BMS for hospital transfusion laboratories, transfusion laboratory managers

Further recommendations are given in Chapter 6. For active recommendations and an update on their progress, please refer to the SHOT website.

7.2. Right Blood Right Patient (RBRP)

Definition

Incidents where a patient was transfused correctly despite one or more serious errors that in other circumstances might have led to an IBCT.

As in previous years reporters have been given the opportunity to separately submit incidents where the right blood was transfused to the right patient despite an error or errors that may have led to the unit being rejected or an incomplete documentation trail being available for that transfusion episode. These errors do not fit into the definition of IBCT but have been included to inform practice. They are not included in the overall numbers of IBCT cases. There are 136 cases in the 2010 report, representing a slight decrease in this category from 2009. This section describes the findings from 136 completed questionnaires.

Table 26
RBRP episodes *n* = 137

Elements that were wrong on blood packs, documentation, identity bands, etc	2009	2010
Name alone or with other elements	43	27
Date of birth alone or with other elements	33	38
Gender	0	1
Hospital or NHS number	17	17
Transposed labels (including donation/pack labels) on 2 or more units for the same patient	34	25
Miscellaneous		
Failure to use address as defined in hospital policy	2	2
Wristband missing or wrong wristband in place at final bedside checking procedure	4	4
No final patient ID check undertaken prior to administration of component	0	1
Incomplete or no ID tag issued with component	4	3
Incomplete issue procedures undertaken	3	2
Incomplete patient details on request form, prescription form or transfusion record	2	12
Incorrect traceability slip issued	0	1
Component issued with two ID label/tags for different patients	0	2
Component issued on inappropriate flag entered in laboratory IT system	0	1
Incorrect component selected from controlled temperature storage (CTS)	0	1
Total	**142**	**137**

Despite emphasising in previous reports that all staff participating in the transfusion process have a personal and professional responsibility to ensure that they have completed the appropriate training, been competency assessed and that they undertake the correct patient ID procedures, these errors continue to be reported.

As in 2009 we have chosen to highlight a number of cases from the clinical and laboratory areas that demonstrate how errors went undetected or were ignored despite staff having a number of opportunities to identify them and take corrective action.

Case 1

Blood component issued to the clinical area with two labels

The laboratory was phoned by a member of the ward nursing staff concerned about the safety of a blood unit issued to their unit. The unit was labelled with the details of another patient. The nurse immediately contacted the laboratory. It transpired that the laboratory did not have a formal policy for removing the labels from non-transfused blood components returned to CTS or for the final patient ID check prior to issue of the component.

This case highlights the need to have formal written procedures available when issuing blood components and that training and competency assessment must cover basic checking procedures.

Case 2

Wrong patient details entered on PAS system

The patient was noted to have the wrong date of birth (DOB) on their ID wristband despite having been previously transfused with FFP and platelets. Further investigation revealed the wrong DOB had been entered onto the computer system on admission to the ward; the wristband was subsequently printed from the ward computer system. The patient was initially confused and unable to verbally confirm his DOB. Later when able to verbally confirm his DOB the error was noted, post transfusion.

It is essential to formally verify patient ID details on admission with a relative or carer for vulnerable patients; where this is not possible, the details should be checked and any discrepancies remedied as soon as possible.

Case 3

Incorrect addressograph label in patient case record

An addressograph label used on the blood component prescription form and transfusion record did not correspond with the details of the patient receiving the transfusion. The error was not noted until a few days after the transfusion was given. All details on the blood component label and blood pack did correspond, therefore the right patient did get the right blood.

This case stresses the importance of checking the patient details when using electronic printouts and checking the information either with the patient or against the ID wristband (or equivalent) before adhering to transfusion documentation, e.g. transfusion record, request form.

Case 4

Transposed blood component label

A patient was crossmatched for 3 units of red cells. The BMS in the hospital transfusion laboratory was undertaking the crossmatch during a busy lunchtime period on a Friday afternoon. An incident occurred whereby the blood component labels on 2 units were transposed when attached to the units (correct patient, incorrect unit number). The error was not noted by two members of nursing staff undertaking the bedside check of the first unit. The error was noted by another two members of nursing staff undertaking the bedside check of the second unit.

Failure in manual checking procedures is a frequently reported adverse event; attaching component/traceability labels to multiple units remains a significant concern, as does the manual checking process when inputting patient details and unique identifiers into the laboratory IT system and issuing blood components. Laboratory and clinical staff should use a logical checking process, defined in their local procedure manual, every time.

COMMENTARY

As reported in previous years, cases of RBRP received in 2010 once again show evidence of staff failing to undertake crucial ID procedures during the transfusion process. All these errors could have been prevented. We make no apology for reiterating yet again that **everyone participating in the transfusion process has a personal and professional responsibility to adhere to the correct patient ID procedures at all times.**

Learning points

- It is imperative that laboratory staff are extra vigilant when issuing multiple components for the same patient and that a final component/patient ID check is undertaken prior to issue. Hospital transfusion laboratories should consider purchasing label verification software or ensuring that a two-person check of units is undertaken prior to issue.
- It is imperative that staff are vigilant at all times in the laboratory and clinical areas when participating in the patient ID process, especially when the patient is admitted.
- Training and assessment in the laboratory must cover basic manual checking procedures.
- NO wristband (or alternative patient ID) – NO transfusion.

8. Inappropriate, Unnecessary and Under/Delayed Transfusion (I&U)

Definition

- Transfusions given on the basis of erroneous, spurious or incorrectly documented laboratory testing results for haemoglobin, platelets and coagulation tests.
- Transfusions given as a result of poor understanding and knowledge of transfusion medicine, such that the decision to transfuse puts the patient at significant risk or is actually harmful.
- Under-transfusion or delayed transfusion resulting in poorer patient outcome.

DATA SUMMARY

Total number of cases	**110**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**91**	Deaths due to transfusion	**0**
		FFP	**11**	Deaths *probably/likely* due to transfusion	**0**
		Platelets	**6**	Deaths *possibly* due to transfusion	**2**
		Cryoprecipitate	**2**	Major morbidity	**4**
		Unknown	**0**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**41**	≥18 years	**98**	Emergency	**41**	A&E	**9**
Female	**64**	16 years to <18 years	**2**	Routine	**63**	Theatre	**7**
Not known	**5**	1 year to <16 years	**9**	Not known	**6**	ITU/NNU/HDU/recovery	**1**
		>28 days to <1 year	**0**			MAU	**15**
		Birth to ≤28 days	**1**	In core hours	**70**	Wards	**64**
		Not known	**0**	Out of core hours	**37**	Community	**1**
		Total	**110**	Not known	**3**	Outpatient/day unit	**0**
						Not known	**2**

MAU, Medical Assessment Unit

There has been a further increase in the number of reports to this category, from 92 in 2009 to 110 this year. This includes 2 cases of delayed transfusion following the initiation of a major haemorrhage procedure.

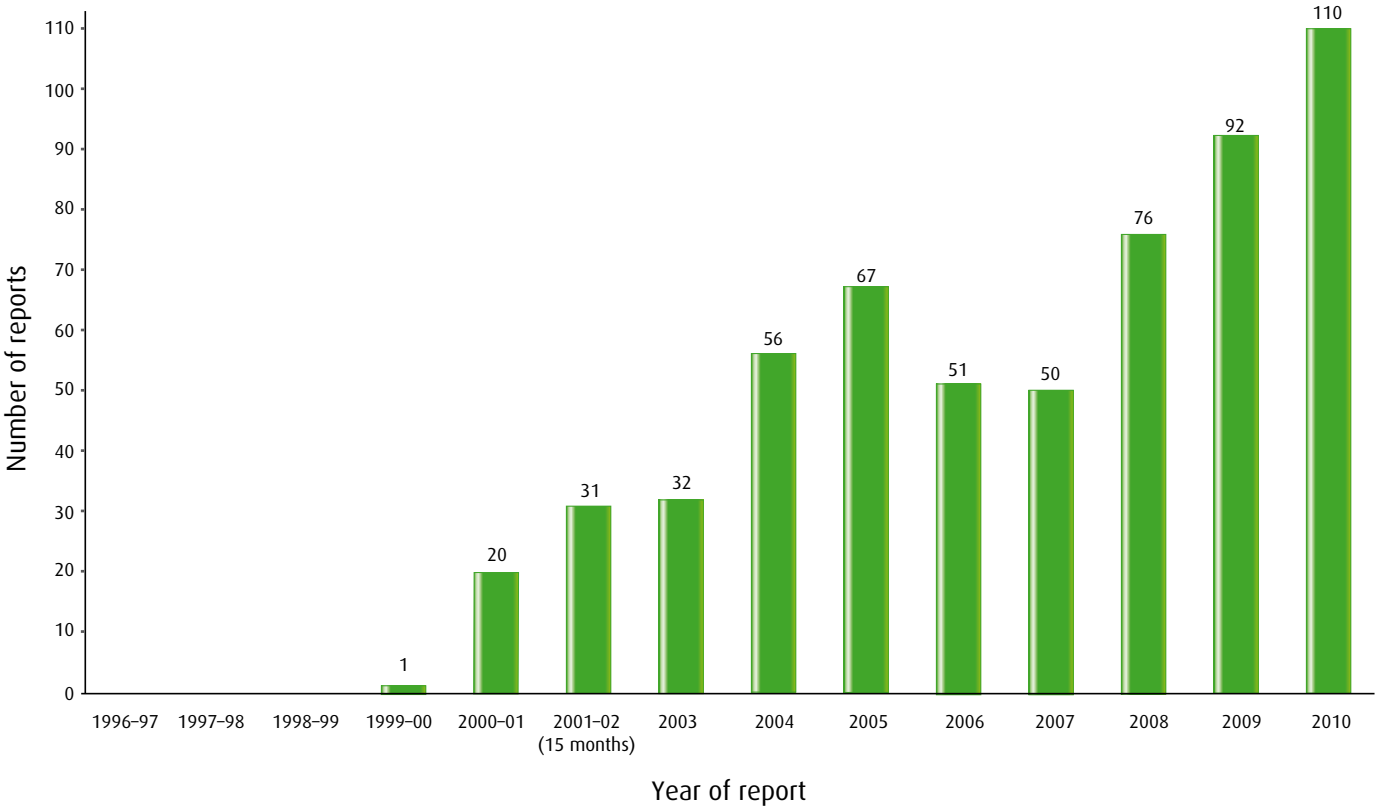
Overall mortality *n* = 2

There were 2 deaths in this group in which the management of the transfusion episode possibly contributed to the death of the patient (imputability 1). One relates to the over-transfusion of red cells and in the second a delay in initiating the major haemorrhage procedure could have contributed to the patient's outcome.

Overall morbidity *n* = 4

There were 4 cases in which the over-transfusion of the patient caused morbidity, including 1 paediatric case, which is discussed in more detail on page 123.

Figure 6
Cases of inappropriate and unnecessary transfusion 1996–2010



INAPPROPRIATE AND UNNECESSARY TRANSFUSION *n* = 108

Mortality *n* = 1

Case 1

Failure to monitor the transfusion requirements during a GI haemorrhage

An elderly patient was admitted to the MAU with a haematemesis and an initial Hb of 10.6 g/dL. No details are provided of her observations or the findings on endoscopy but she had further episodes of vomiting blood. Five units of red cells were transfused before a repeat Hb was performed, which was 20.4 g/dL. The patient was recognised to have circulatory overload and died shortly thereafter.

This patient was inadequately monitored from a laboratory perspective. Although in a massive haemorrhage situation it is acceptable to repeat the laboratory tests after transfusing 4 units of red cells (with other components), in cases where there is lesser haemorrhage, more frequent monitoring is required.

Major morbidity *n* = 4

Three cases are reviewed below and the fourth, involving a premature neonate, is discussed on page 123.

Case 2

Over-transfusion requiring venesection

An elderly patient with a severe GI bleed had repeat Hbs of 6.1 and 6.4 g/dL. Six units of red cells were transfused prior to rechecking the Hb, which was 17.1 g/dL. The patient developed circulatory overload and required venesecting 2 units.

This case is comparable with Case 1 and the same lesson applies. In this year's report, 7 out of the 11 instances of patients being excessively transfused were due to infrequent monitoring of Hb in patients with GI haemorrhage.

Learning point

- Patients with GI bleeding not meeting the criteria for massive haemorrhage must have frequent monitoring of their Hb.

Case 3

Unnecessary transfusion based on the Hb result from WBIT

Patient A with obstructive jaundice secondary to a pancreatic mass had an Hb of 10 g/dL. A crossmatch was requested for Patient B, who shared the same blood group and had an Hb of 6 g/dL but was labelled with Patient A's details. Patient A was prescribed 3 units of red cells, became hypoxic after the transfusion of the first and required ventilation. TRALI was suspected but not confirmed on serology. (No details of CXR given.) The patient's subsequent death was unrelated to the transfusion.

The primary error was WBIT, which could not be detected in the laboratory due to the 2 patients having the same blood group. However, the second error relates to prescribing blood for a patient who clearly was not in need of transfusion, suggesting that the doctor neither knew the patient nor reflected on the known Hb of the patient when prescribing the blood.

Case 4

Over-transfusion leading to polycythaemia and a cerebral infarct

An elderly female patient of low body weight (29 kg) was admitted with an initial Hb of 7 g/dL. Three units of red cells were prescribed and the post-transfusion Hb was 17 g/dL, confirmed with a repeat sample the following day. She sustained a cerebral infarct 48 hours following the transfusion, which resulted in long-term morbidity. The reporters were apparently very confident of the initial Hb and felt that an inappropriate volume had been prescribed.

If the empirical paediatric formula[1] of (desired Hb g/dL – actual Hb g/dL × weight in kg × 3) had been applied in prescribing for this 29 kg patient, she would only have been given 261 mL red cells in optimal additive solution (OAS) to raise her Hb from 7 g/dL to 10 g/dL. She received, however, 3 units of red cells (approximately 900 mL), which on applying the formula gives a predicted increment in Hb of 10 g/dL, as seen here. There are no studies that confirm the validity of using this paediatric weight-related formula when prescribing red cells for adults. A previous study in adults has applied the patient's body weight and predicted blood volume in conjunction with the Hb content of the units of red cells to calculate the number of units to be transfused,[2] but this approach is not practicable in a routine setting. However, the notion that 1 unit of red cells gives an approximate increment in Hb of 1 g/dL in all adults is flawed and can lead to over-transfusion in low body weight patients. A trial applying the paediatric formula for prescribing red cells in adults is warranted.

Transfusions based on wrong Hb, platelet or coagulation result *n* = 56

Table 27
Transfusion based on wrong Hb result *n* = 48

Clinical causes of falsely low Hb value	No. of cases
Falsely low Hb due to phlebotomy from drip arm or 'diluted sample' with repeat requested by laboratory	6
Faulty sample (clotted, short, etc.), laboratory requested a repeat but request ignored and wrong blood result used	7
Transfusion based on an old Hb although a more recent result was available	4
Hb result belonged to another patient (including 3 WBIT)	9
Blood gas machine Hb used	5
Erroneous result from POCT Hb estimation device	3
Incorrect POCT device used (measured glucose rather than Hb)	1
Unauthorised results viewed from ward and acted on	1
Substitution of white cell count (WCC) for Hb (transcription error)	3
Verbal miscommunication of results	3
Haematology laboratory causes of falsely low Hb result	
Hb reported from blood-stained pleural tap, but source of sample not reported to ward	1
Authorised results from mis-sampling reported	1
Authorised result from clotted sample	1
Other	1
Unknown	2
Total	**48**

The most common cause of an incorrect Hb relates to a problem with the sample, either diluted due to being taken from a drip arm or in other ways inadequate. Without exception, laboratory staff appreciated that there could be a problem but transmitted the result to the clinical area with advice that a further sample should be taken. However, this advice was overlooked by the clinical teams. Furthermore in many cases there was no assessment of these laboratory results with respect to historical results or the clinical condition of the patient.

A second common error related to the incorrect transmission of verbal results provided by the laboratory. These results were either assigned to an incorrect patient or the values given were recorded incorrectly at the clinical end. CPA standard (G3) requires that the laboratory establishes a procedure when giving telephoned results for ensuring a confirmation of correct transmission.[3]

There is still evidence that blood gas machines are being relied on for measurement of the Hb on which to base the decision for transfusion. These instruments produce a calculated Hb result that for many reasons may be inaccurate. POCT in use within an organisation should be governed by the quality framework described in the CPA additional standards.[4]

The following case illustrates the dangers of untrained personnel having access to using such equipment.

Case 5

Lack of POCT device knowledge leads to erroneous result and transfusion

A consultant anaesthetist anaesthetised a paediatric patient for a procedure. Halfway through surgery it was estimated the patient had a blood loss of approximately 700 mL and he asked the operating department practitioner (ODP) for a POCT Hb estimation. The ODP returned from recovery to state that they did not have the model requested but a different model was available. The ODP assumed that this was an alternative device for Hb estimation. It was in fact a device for checking blood sugar.

The result of 7.2 was consistent with clinical suspicion and the anaesthetist requested blood on this basis. After 100 mL of blood had been transfused the ODP informed him that they had checked with recovery staff and the machine used was for blood sugar testing. The transfusion was stopped and a sample was sent to the laboratory. The result was 11.6 g/dL.

Table 28
Causes of falsely low platelet count *n* = 6

Causes of falsely low platelet count	No. of cases
Platelet clumping	3
Clot in sample	1
Analyser error	2

Table 29
Causes of incorrect coagulation results *n* = 2

Causes of incorrect coagulation results	No. of cases
WBIT	1
Unauthorised results viewed in ward and acted on (sample clotted)	1

Learning points for laboratories

- 12% of unnecessary transfusions could be avoided if laboratories did not transmit results they know or suspect to be inaccurate, but instead requested a second sample.
- A further 12% of unnecessary transfusions could be avoided if laboratories required confirmation of correct transmission of telephoned results.

Transfusions based on poor basic knowledge, incorrect decision making or poor prescribing *n* = 52

Table 30
Categories of poor knowledge or prescribing *n* = 52

Categories of poor knowledge or prescribing (excluding use of erroneous Hb)	No. of cases
Excessive volume/rate of red cells transfused to infant or child	3
Excessive red cell transfusion resulting in Hb above the normal range	11
Transfusion of red cells for chronic iron deficiency	9
Inappropriate transfusion of patient with megaloblastic anaemia	1
Incorrect component requested and given	4
FFP transfused to patient on warfarin with prolonged international normalised ratio (INR) but no bleeding	3
FFP transfused to patient with normal coagulation screen	2
FFP and platelets prescribed despite normal results	1
Use of flying squad when crossmatched units or valid group and screen were available	6
Transfusion of an asymptomatic patient with correctable anaemia	3
Red cells transfused that were not prescribed	2
FFP transfused that was not prescribed	1
Overnight transfusion for patient for whom a transfusion had previously been deemed not necessary	2
Red cells prescribed for incorrect patient	2
Inappropriate transfusion for patient with chronic renal failure	1
Incorrect (double dose) FFP prescribed	1
Total	**52**

It has been noted from the cases of morbidity and mortality above that over-transfusion in adults is usually due to a failure to frequently monitor patients who have ongoing blood loss. A second cause of over-transfusion relates to a lack of knowledge of prescribing for paediatric cases, which is discussed further on page 123.

A total of 14 patients received transfusions with no justification.

Nine patients with chronic iron deficiency were transfused, the majority of whom were asymptomatic. Several were referred by their general practitioners (GPs) to a MAU with a specific request for transfusion rather than being referred to a haematologist for further advice or parenteral iron. In 1 case, a previous decision taken in hospital not to transfuse was over-ruled on discharge into the community.

Case 6
Patient given a transfusion despite responding to oral iron
Following iron deficiency during pregnancy, a female delivered with an Hb of 7.8 g/dL. A decision was taken in conjunction with the patient not to transfuse her, but to discharge her on oral iron. Nine days later, her Hb was checked by the midwife and found to have risen to 8.9 g/dL. Two weeks later, without a further check on her Hb, she was admitted to the community hospital for a blood transfusion at the GP's request.

Three young patients who were anaemic post-operatively and were asymptomatic were also transfused unnecessarily as was a patient with asymptomatic megaloblastic anaemia. The final patient had chronic renal failure and a stable Hb and the transfusion was prescribed by a FY2 doctor without consultation with senior colleagues.

Learning point

- Patients referred by their GPs to A&E or MAUs for blood transfusion must be referred to a haematologist.

Case 7

Lack of communication between shifts

A patient with known hereditary spherocytosis was admitted with an Hb of 7.2 g/dL. The consultant haematologist decided in consultation with the patient that a transfusion was not necessary. However, the low Hb was noted by a nurse on night shift who informed the on-call doctor, who then prescribed 4 units of red cells. Two were given overnight before the decision to stop transfusing was taken the following day.

This is 1 of 2 cases where a decision taken during the day that was documented in the case notes was overlooked by night staff. This shows a concerning lack of continuity of patient care and unnecessary transfusions being given out of hours. The on-call doctor appears to have had no knowledge of the patient or the condition and is unlikely to have had sufficient time in an on-call situation to review the clinical need for blood.

Case 8

Incorrect component type requested and transfused despite a lack of prescription

A patient's potential need for blood components was discussed with the nurse practitioner. The doctor verbally mentioned FFP but prescribed blood and platelets, and documented this prescription in the notes. The nurse practitioner thought that as she had been trained to take a G&S sample she was then able to request components and proceeded to send a request to the hospital transfusion laboratory for platelets and FFP.

The FFP when thawed was checked at the bedside by two nurses who both signed, dated and timed the traceability label and medication chart. However, neither nurse noted that there was no prescription for the FFP, which was administered. The error was noticed when a third nurse replaced the patient's venflon and noticed the empty FFP bag hanging on the stand.

This case is disturbing in that the nurse requested blood components without being trained and assessed as competent for this task. In doing so a request was made for a component that was neither prescribed nor documented in the case notes. A further error was made by the nurses administering the FFP in the absence of a prescription. There were a number of points in the process where the incorrect transfusion could have been prevented but these were overlooked.

There were 2 further examples of nurses transfusing all the red cells that had been crossmatched by the laboratory even though not all of the units had been prescribed.

Learning point

- In a non-urgent situation, no prescription – no transfusion.

Case 9

Transfusion of unnecessary components and with inappropriate doses

A patient was bleeding after a sub-total colectomy and a request was made for 2 doses of platelets and 2 units of FFP. The patient had a normal platelet count (245 × 10^9/L) and a normal INR of 1.2. The doctor did not check these results. The BMS did not telephone these results to the doctor or contact the consultant haematologist in order to challenge the inappropriate decision.

With the exception of when dealing with a massive haemorrhage, there is never any justification for requesting platelets and FFP for a bleeding patient without taking into account the current laboratory results. Furthermore there was a lack of knowledge of the appropriate doses of these two components. Although the responsibility for these errors rests with the clinician, the BMS missed the opportunity to communicate the normal results and to question the request given the findings, prior to issuing the unnecessary components.

Learning point

- In accordance with Better Blood Transfusion 2007/001, protocols should be in existence which empower laboratory staff to question the appropriateness of requests for transfusion.[5]

Case 10

Lack of communication leads to the unnecessary use of emergency O RhD negative red cells

A patient with a GI bleed had a group and screen sample taken the previous evening that had been processed by the laboratory. However, without contacting the laboratory, the clinical staff proceeded to transfuse emergency O RhD red cells the following day.

This is 1 of 6 cases in which the clinical team transfused emergency O RhD negative red cells when compatible units could have been available within minutes. It is possible that in these cases that there was no awareness by the clinical team that a sample had previously been taken or that there was no understanding of the time frame of responsiveness of the laboratory to provide either group specific or compatible units. In either instance, there was an absence of communication from the clinical team to the laboratory.

UNDER AND DELAYED TRANSFUSION *n* = 2

Mortality *n* = 1

Case 11

Lack of knowledge of how to initiate the major haemorrhage protocol in A&E

At 20.01 a middle-aged male was admitted to A&E with a Glasgow Coma Score (GCS) of 3/15 and received 1 L colloid. A sample was taken for G&S within 10 minutes of arrival, which was booked into the laboratory at 20.20. At 20.30 the patient had a pulseless electrical activity (PEA) arrest and a further litre of colloid was infused, and at 20.40 he sustained a massive haematemesis.

No Incident Communication Coordinator had been identified in A&E and the alarm to alert the transfusion laboratory to activate the major haemorrhage protocol was not raised. The clinical staff in A&E were unaware of how to access the emergency O RhD negative units and the porter arrived at the transfusion laboratory at 20.50 to collect 2 such units. A further 2 units of red cells were then requested and issued as group specific at 21.10. The clinicians also requested FFP and cryoprecipitate but the BMS referred to the major haemorrhage protocol then in existence, which required that a coagulation screen should have been interpreted by a haematologist prior to releasing these components. The patient subsequently arrested and died at 21.30, having received 10.5 L of colloid and 4 units of red cells.

An internal investigation concluded that this incident constituted a serious systems failure due to a lack of familiarity and understanding of the Trust's major haemorrhage policy among clinical staff and that communications between all parties had been poor in the absence of a coordinator. It also highlighted the need to consider a more aggressive blood loss policy. The man died from a massive haemorrhage from a major vessel and it is uncertain whether the timely provision of relevant blood components would have affected the outcome. Nevertheless, this patient with massive blood loss received totally inadequate blood component support over a period of 1.5 hours.

The Trust is conducting a multidisciplinary review of its policy for the management of major haemorrhage, in line with the recommendations of the NPSA Rapid Response Report 2010/017,[6] which will include the need to monitor laboratory tests results frequently, but will advocate providing component support in keeping with the patient's blood loss rather than awaiting authorisation of their release on the basis of test results. It will also consider the need to locate emergency O RhD negative units in the A&E department.

Case 12

Delay in obtaining units following major haemorrhage protocol being initiated

A child involved in a road traffic accident (RTA) was found to be asystolic at the scene and cardiopulmonary resuscitation (CPR) was commenced. The ambulance staff had alerted A&E to major blood loss and had requested blood to be available there on arrival. The major haemorrhage protocol, however, required a unique patient number to be allocated prior to issuing emergency O RhD negative units from the transfusion laboratory and it took 15 minutes following the patient's arrival in A&E for any red cells to be made available. The trauma team felt that this delay was unacceptable and the major haemorrhage protocol has since been reviewed.

In this case the lack of immediate red cell support would not have influenced the outcome. However, it does demonstrate the need to balance the requirement for confirmation of patient identity prior to releasing blood with the urgent requirement of red cell support in a massive blood loss situation. Although traceability of all blood components is of paramount importance, this requirement must not stand in the way of resuscitative measures since it can be undertaken in parallel or even retrospectively.

COMMENTARY

The number of reports of I&U transfusions continues to rise with similar findings to previous years with respect to the causes of misleading laboratory results. There is also evidence of lack of knowledge among medical staff in that red cell transfusions are being given unnecessarily for correctable anaemias and other blood components are prescribed inappropriately. This year there are also cases in which inadequate handover between clinical teams appears to be in evidence, including the following examples:

- Previously made and documented decisions are overturned between shifts.
- Red cells are prescribed for the incorrect patient.
- The incorrect component is prescribed for the correct patient.
- Emergency O RhD negative blood is used when there is a lack of appreciation that compatible blood is or can be made available from the laboratory.

This year has also witnessed 2 reports of delays in accessing emergency O RhD negative red cells. In 1 case this delay could possibly have influenced the outcome. While there has been a tendency to reduce the number of satellite fridges in hospitals in order to comply with MHRA requirements and to minimise the wastage of emergency O RhD negative red cells, those without cold storage facilities in A&E and maternity units must ensure that their major haemorrhage procedures do not compromise the resuscitative requirements of the clinical teams.

Recommendations

- Every Trust/hospital must ensure compliance with CPA standards when giving telephoned results, in obtaining confirmation of the correct transmission.

  Action: Leads/directors of pathology

- Every Trust must review its major haemorrhage protocol to ensure that it meets the recommendations of the NPSA Rapid Response Report 'The transfusion of blood and blood components in an emergency' NPSA/2010/017.[6]

  Action: HTCs

- All nurses and midwives making the clinical decision and providing the written instruction for blood component transfusion must operate within a governance framework ratified by the Trust and be aware of their professional accountability.[7]

  Action: HTCs, clinical governance committees

- Handover information must include the decisions that have been taken with respect to transfusion support and the laboratory tests that have been requested.[8]

  Action: Clinical governance committees

For active recommendations and an update on their progress, please refer to the SHOT website.

9. Handling and Storage Errors (HSE)

Definition

All reported episodes in which a patient was transfused with a blood component or plasma product intended for the patient but in which, during the transfusion process, the handling and storage may have rendered the component less safe for transfusion.

DATA SUMMARY

Total number of cases	**239**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**212**	Deaths due to transfusion	**0**
		FFP	**14**	Deaths *probably/likely* due to transfusion	**0**
		Platelets	**12**	Deaths *possibly* due to transfusion	**0**
		Other (granulocyte)	**1**	Major morbidity	**0**
		Unknown	**0**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**108**	≥18 years	**206**	Emergency	**53**	A&E	**7**
Female	**117**	16 years to <18 years	**1**	Routine	**147**	Theatre	**12**
Not known	**14**	1 year to <16 years	**5**	Not known	**39**	ITU/NNU/HDU/recovery	**31**
		>28 days to <1 year	**4**				
		Birth to ≤28 days	**2**	In core hours	**131**	Wards	**169**
		Not known	**21**	Out of core hours	**98**	Community	**4**
		Total	**239**	Not known	**10**	Outpatient/day unit	**5**
						Not known	**11**

There were 12 HSE cases that involved paediatric patients and 21 that were unknown; all other cases were in adults over 18 years of age. In keeping with previous years, 62% of the incidents occurred in a routine setting, 22% were emergencies and 16% were unknown. There were no transfusion-related cases of morbidity or mortality reported. Table 31 illustrates the circumstances in which these HSE incidents took place.

Table 31
Categories of HSE

Type of case	**2009**	**2010**
Technical administration error	12	18
Transfusion of expired red cells	31	29
Excessive time to transfuse	69	116
Cold chain error	84	73
Additional cases		
Transfusion of a unit where the interval between sampling and transfusion exceeds BCSH guidelines or a risk-assessed local policy	n/a	3
Total	**196**	**239**

Technical administration errors *n* = 18

There were 18 technical administration errors, an increase of 50% from 2009. The majority of cases (61%, *n* = 11) resulted from staff using the wrong type of giving set. There were 2 interesting cases reported in 2010 (see below).

Case 1

Neonate fails to respond to transfusion of red cells

A top-up transfusion of 14 mL of RBCs administered to a neonate failed to increase the neonate's Hb, despite receiving a second aliquot of 14 mL. On investigation it is thought that the roller clamp between the Y-connection and the syringe driver may not have been fully engaged, resulting in the red cells being drawn back into the red cell unit.

Case 2

White cell transfusion – exchange of bags

A white cell transfusion was requested for a patient. The component provided did not have an appropriate port. Due to the patient's deteriorating condition and concern over the expiry time, the port was cut and the blood decanted into a sterile receptacle, then into a sodium chloride bag that had had the sodium chloride removed. The component was then transfused using a blood giving set.

It is imperative that there is a robust local policy in place detailing where staff experiencing a problem while transfusing a blood component/product can access relevant advice, including out of hours. Should a member of staff experience any technical problem with a medical device or equipment associated with the transfusion process they should consider reporting the adverse event via the MHRA medical devices online reporting system (www.mhra.gov.uk).

Transfusion of expired blood components *n* = 29

There were 29 cases of expired units being transfused, a slight reduction of 6% compared to last year. The majority of errors, however, were caused by components being issued with a short expiry time, usually less than 24 hours. As in previous years, despite staff being aware of the short expiry time/date, delays due to technical issues or changes in the patients' condition have led to prolonged interruptions or hold-ups prior to commencing the transfusion. On investigation, some members of the night staff reported a failure to note the change in date during their shift period, which led to the transfusion of expired blood components.

Other causes included failure to clear satellite fridges and thawing plasma components before the patient was ready to commence the transfusion.

Excessive time to complete administration of blood components *n* = 116

This category has seen a massive increase of 68% in the number of reports from 2009. There were 116 cases where the administration of a blood component took longer than the recommended time to transfuse; the recommended transfusion times for all blood components can be found in the BCSH Guideline on the Administration of Blood Components.[1] Undoubtedly monitoring and auditing of traceability practices either using the 'Bag & Tag' or electronic blood tracking systems has contributed to this increase in reporting. This year we were able to differentiate between cases where the error was caused by excessive time out of CTS (*n* = 17) and excessive administration time (*n* = 99). In 20 cases excessive times were reported in both categories. In 3 cases the transfusion overran by more than 10 hours whereas in 22 cases the transfusion overran by less than 30 minutes. In 46% of cases the transfusion took place out of core hours (between 20.00 and 08.00 hours) (see Table 32).

Case 3

Remember to observe the patient

A unit of red cells was commenced on an elderly male patient at 05.30 for acute blood loss. At 20.30 the ward staff contacted the laboratory to say the blood transfusion was still running. On investigation it was noted that NO observations had been recorded following the 15 minute post-transfusion check.

It is essential that all patients are monitored throughout the transfusion event; this includes regular visual observations, when many of these errors could have been detected and corrective action taken.[1]

Table 32
Breakdown of working hours during which transfusion times were excessive *n* = 116
NB Not given in 2 cases

Time period	In core hours/out of core hours	Number
08.00 to 20.00	Core hours	62
20.00 to 00.00	Out of core hours	30
00.00 to 08.00		22

COMMENTARY

The learning points from previous SHOT reports remain pertinent and it is strongly recommended that practitioners review these by visiting the SHOT website. Clinical staff should be encouraged to contact their transfusion practitioner or hospital transfusion laboratory if they need clarification or advice on any matters related to the transport, storage or administration of blood components.

Cold chain errors *n* = 73

Table 33
Summary of cold chain related errors

Type of error	No. of cases 2009	No. of cases 2010
Alarm related *(where staff failed to carry out the correct procedure following an alarm being set off on a refrigerator)*	5	9
Equipment failure *(as a result of either a power failure or suspected refrigerator failure which failed to activate the alarm)*	7	17
Transport or delivery of components	10	2
Inappropriate storage of components	62	45
Returned to: *a) stock when they should have been discarded* *b) satellite fridge when they should have been discarded*	 *31* *3*	 *8* *4*
With no/incomplete/inaccurate cold chain documentation/traceability	*8*	*18*
Stored inappropriately in clinical area, e.g. out of order refrigerator, transport box, non-validated transport box/storage, unknown	*20*	*15*
Total	**84**	**73**

The number of HSE incidents that resulted from cold chain errors in 2010 has decreased by 13% when compared to 2009 (see Table 33).

This year 26 equipment-related incidents were reported, which subsequently resulted in red cell components that were stored at inappropriate temperatures being transfused to a number of patients (see Table 33).

A total of 47/73 (64%) of the errors involved patients receiving 1 or more units of RBCs, platelets (6 cases) and FFP (5 cases), which had been either inappropriately transported or had been out of CTS for more than 30 minutes and then returned to CTS.

Case 4

Communication failure results in inappropriate transport of RBCs

The blood transfusion laboratory received a telephone request for 4 units of blood at 12.40; blood was subsequently issued at 12.47. At approximately 14.00 the laboratory received a telephone call asking if blood was ready to collect, as the patient was being transferred to another hospital. The laboratory was unaware of this, and had not been informed of this during the telephone request and hence did not pack the blood appropriately. The BMS on duty informed the ward that it would take 10–15 minutes to package the blood and issue the appropriate documentation. When the BMS went to remove the blood from the issue fridge for packing the blood had already been removed. The BMS phoned the ward and was told that the blood was removed at 14.17 as the patient had left via ambulance and the blood had gone with him. The receiving hospital contacted the BMS on duty to inform them that 1 unit had arrived with the patient and had been transported in a carrier bag.

Effective communication is important when delivering optimum care, but is vital in situations where a change in the patient's condition may require a rapid response.

This year has seen an increase (>100%) in incomplete cold chain documentation errors to 18 in 2010 compared with 8 in 2009.

Failure to maintain an adequate or complete cold chain record can result in transfusion of a unit that has been out of CTS for a long period of time, or unnecessary wastage of blood components. It is important to document the storage and transportation of all blood components as this acts as a communication link between clinical and laboratory staff when determining the fate of a unit.

As mentioned in the 2009 SHOT report, it is fundamental to ensure that effective bedside checks are performed and the necessary documentation verifying the storage, transportation and administration of the blood component is completed for every transfusion episode. The use of a transfusion record would assist in improving documentation; examples can be found on the transfusion guidelines website.

In 2010 we have identified a number of cases whereby a unit of RBCs was transfused when it should have been cleared from a satellite blood fridge as the interval between sampling and transfusion had exceeded BCSH guideline recommendations.[2]

Case 5

Patient transfused >72 hours after crossmatch

Patient receiving emergency transfusions in surgical HDU on 10/04/2010 required 7 units in total before sample was insufficient to process further units. New sample was received on 10/04/2010 at 23.20, and a further 4 units were requested. The BMS prepared the units and issued them to the satellite fridge. The units were not transfused immediately and remained in the satellite fridge >72 hours after the first unit had been transfused (the units should have been removed by 23.20 on 13/04/2010 and a fresh sample should have been requested if further blood was required). The surgical HDU transfused all of these available units between 23.00 on 14/04/2010 and 06.35 on 15/04/2010.

COMMENTARY on cold chain errors

There has been an overall decrease in the number of cold chain errors reported in 2010 compared with 2009. Nevertheless this has come from considerable decreases in certain errors, such as those associated with transport and delivery, and those involving inappropriate storage of components. However, there have been notable increases in errors involving equipment failures and once again this year has seen numerous incidents in which cold chain documentation has either been missing or incomplete, resulting in components that may have been stored at inappropriate temperatures subsequently being transfused to patients. Further examples of cold chain errors were noted as near miss (see page 136).

Additionally, communication is equally important between clinical and laboratory staff, especially with numerous errors related to red cell components being transfused to patients in which the time since sampling exceeded the recommendations as stated in the BCSH guidelines.[2] For a more comprehensive update on what are seen to be SHOT reportable HSE errors, please refer to the categories document on the SHOT website.[3]

All staff should be reminded that they have a professional responsibility to practise safely, and to ensure that their knowledge and skills are kept up to date when participating in the transfusion process. It is important to ensure regular maintenance and checking procedures, including an efficient traceability matrix, are achieved, especially when concerning the storage of blood components to prevent unnecessary wastage. These errors could be due to the lack of training or lack of understanding of the rationale behind the protocols and SOPs in use.

Learning points

- Hospitals should have a robust policy in place for removing expired blood components and components past their suitability date from satellite fridges.
- Effective communication between all staff involved in the transfusion process is vital to prevent unnecessary errors occurring.

Recommendations

There are no new recommendations.

For active recommendations and an update on their progress, please refer to the SHOT website.

10. Adverse Events Relating to Anti-D Immunoglobulin (Anti-D)

Definition

An adverse event relating to anti-D immunoglobulin is defined as relating to the prescription, administration or omission of anti-D immunoglobulin that has the potential to cause harm to the mother or fetus immediately or in the future.

DATA SUMMARY

Total number of cases	**241**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**0**	Deaths due to transfusion	**0**
		FFP	**0**	Deaths *probably/likely* due to transfusion	**0**
		Platelets	**0**	Deaths *possibly* due to transfusion	**0**
		Anti-D Ig	**241**	Major morbidity	**1**
		Unknown	**0**	*Potential for major morbidity*	**165**

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**0**	≥18 years	**235**	Emergency	**0**	A&E	**0**
Female	**241**	16 years to <18 years	**4**	Routine	**0**	Theatre	**0**
Not known	**0**	1 year to <16 years	**2**	Not known	**241**	ITU/NNU/HDU/recovery	**0**
		>28 days to <1 year	**0**				
		Birth to ≤28 days	**0**	In core hours	**41**	Wards	**185**
		Not known	**0**	Out of core hours	**10**	Community	**56**
		Total	**241**	Not known	**190**	Outpatient/day unit	**0**
						Not known	**0**

This section describes the main findings from 241 completed questionnaires. The reports are broken down into the reporting categories shown in Table 34. Under current legislation,[1] adverse events related to the administration of anti-D Ig are reportable as 'SHOT-only'. Clinical reactions to anti-D Ig are reportable via the MHRA 'yellow card' system.

Mortality *n* = 0

There was no known fetal mortality following the omission or delay in administration of anti-D Ig, but these data have not been systematically reported or collected.

Potential for major morbidity *n* = 165

In 165 of the 241 cases anti-D Ig was administered more than 72 hours following a potentially sensitising event (PSE) or omitted altogether, resulting in the potential for sensitisation of the patient to the D antigen. This satisfies the current SHOT definition of potential major morbidity. In 1 case an RhD negative patient aged 18 years was reported to have become sensitised after receiving RhD positive platelets during a trauma-associated transfusion, for which no anti-D prophylaxis was administered.

Figure 7
Cumulative data regarding adverse events relating to anti-D Ig

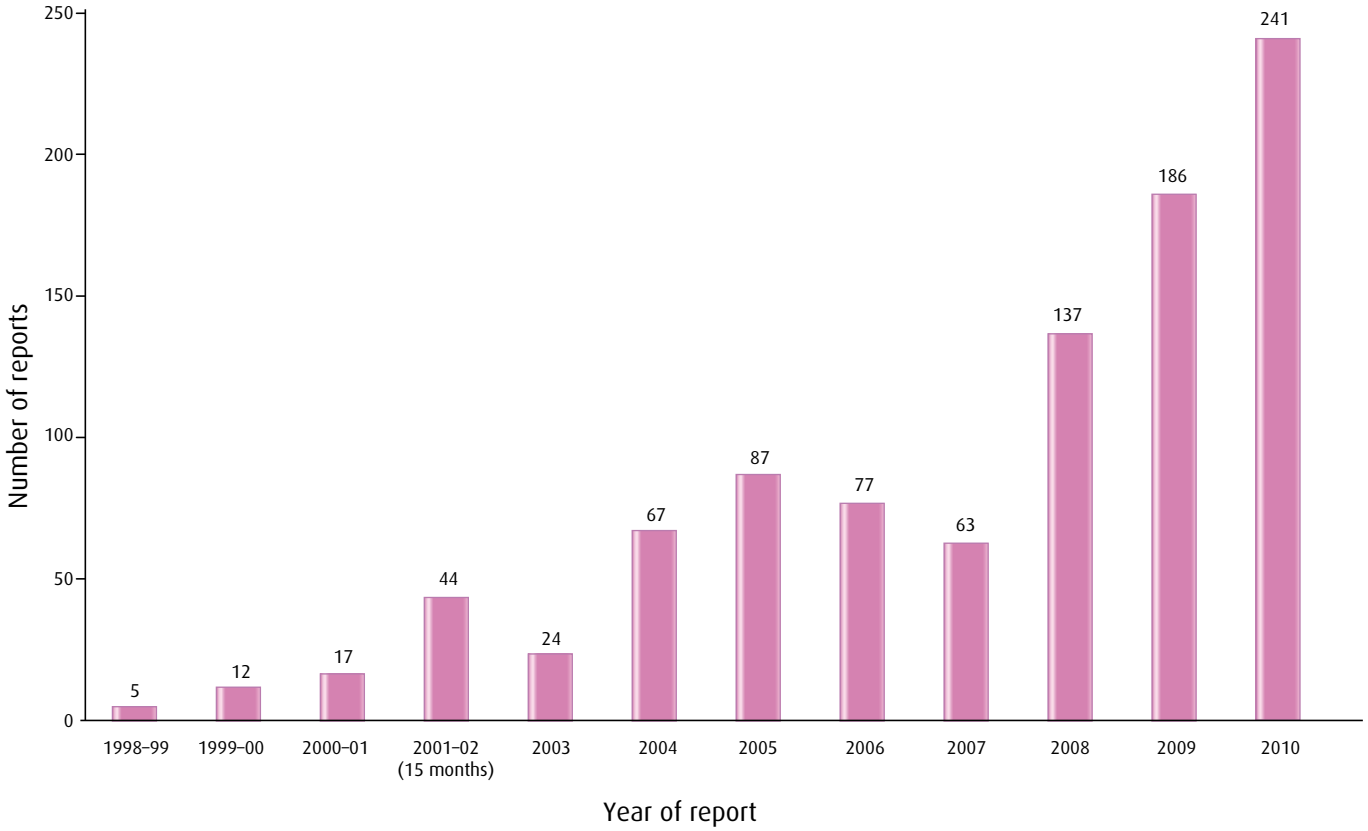


Table 34
Reporting categories of adverse events relating to anti-D Ig

Category of adverse event	No. of cases
Omission or late administration of anti-D Ig	166
Inappropriate administration of anti-D Ig	59
to an RhD positive patient *to a patient with immune anti-D* *to a mother of an RhD negative infant* *given to the wrong patient*	*26* *17* *8* *8*
Wrong dose of anti-D Ig given according to local policy	12
HSE relating to anti-D Ig	4
Total	**241**

Clinical vs. laboratory errors

For the reporting year 2010, 241 events relating to anti-D Ig administration are summarised in Table 35, with a breakdown of the proportion of clinical and laboratory errors that were primarily responsible.

The distribution of cases has in past years reflected general SHOT findings that around 2/3 of reports involve errors by clinical staff and 1/3 laboratory staff. This year, as in 2009, clinical errors accounted for 79% of the total reports relating to administration of anti-D Ig.

Table 35
Adverse incidents involving anti-D Ig administration, with site of primary error

Type of event	Cases	No. of primary errors		
		Midwife	Laboratory	Doctor
Omission or late administration of anti-D Ig	**166**	139	21	6
Anti-D Ig given to RhD positive patient	**26**	13	11	2
Anti-D Ig given to patient with immune anti-D	**17**	9	8	0
Anti-D Ig given to mother of RhD negative infant	**8**	4	4	0
Anti-D given to wrong patient	**8**	7	0	1
Wrong dose of anti-D given	**12**	4	6	2
Anti-D Ig HSE	**4**	2	1	1
Total	**241**	178	51	12

Omission or late administration of anti-D Ig *n* = 166

In 139/166 cases the primary error was made by a midwife. Forty-six cases occurred in the community and 120 in a hospital setting. As in last year's report, there are multiple examples where anti-D Ig has been issued by the laboratory only to be found days or weeks later in maternity fridges, indicating a failure of the discharge checklist and possibly a lack of understanding by some clinical staff of the time limits within which anti-D Ig must be administered.

Case 1
Mis-transcribed group results in omission of prophylaxis
A patient's RhD group was mis-transcribed as positive on the front of her notes, even though all grouping reports from the laboratory clearly stated that the patient was RhD negative. The discrepancy was noted at delivery, but the patient had missed out on any anti-D prophylaxis during her pregnancy.

Case 2
Cord blood group allocated to wrong computer record, resulting in delay in administration
A cord blood group was correctly tested as RhD positive, but the result was erroneously uploaded to the maternal record on the laboratory computer system by a shift BMS who did not normally work in transfusion. The error was only spotted when the clinical area enquired as to why there was no cord group available and why the maternal group was now showing as RhD positive.

Case 3
Change in laboratory reporting procedure results in significant delays in administration of RAADP
A laboratory changed the mechanism of reporting blood groups from paper forms to an electronic system. The community midwives had relied on the paper reports to generate appointment lists for RAADP, but the change in procedure resulted in a series of 15 reports regarding patients whose RAADP was delayed by anything from 1 to 10 weeks, and in 1 case omitted altogether. The laboratory now produces a regular paper list of RhD negative antenatal patients for the midwives.

This case highlights the need for a formal change control process involving all stakeholders when making changes to laboratory procedures.

Case 4

Lack of knowledge around RAADP results in omission of anti-D Ig dose in response to a PSE

A RhD negative patient presented on the labour ward with a significant per vaginam (PV) bleed at 35 weeks' gestation, but the SpR on duty refused to administer anti-D Ig as they were under the impression that RAADP covered all sensitising events up to delivery.

Case 5

Lack of knowledge around anti-D prophylaxis results in omission of routine antenatal anti-D Ig dose

A 1500 iu dose of anti-D Ig was issued to a GP surgery for use as RAADP at 28 weeks' gestation. The anti-D Ig was returned unused as the patient had previously received prophylaxis for a PSE while in hospital and the midwives thought the further dose was not necessary.

Learning point

- Anti-D Ig must still be administered in response to a PSE even if the patient has received, or is due to receive, RAADP. RAADP must still be administered at the appropriate time, even if the patient has recently received anti-D prophylaxis for a PSE.

Inappropriate administration of anti-D Ig *n* = 59

This group is further subdivided into four categories.

Anti-D Ig given to RhD positive patients *n* = 26

Overall 15/26 errors were clinical: 13 by midwives and 2 by a doctor. Eleven of the 26 primary errors arose in the laboratory. Of the 26 errors, 24 were made in the hospital setting and 2 in the community.

Case 6

Anti-D Ig issued to a patient on the basis of an old result and rapid confirmatory test

Anti-D Ig was issued by the laboratory on the basis of an RhD negative grouping result from 10 years earlier, confirmed by a rapid spin test on the current sample. Routine grouping of the sample later showed that the patient was weak RhD positive.

The patient in this case received anti-D Ig, which was undoubtedly the correct outcome, but this case highlights the inappropriate use of manual spin tests, which have repeatedly been demonstrated to be less robust than routine laboratory testing.

Case 7

Failure to check the computer record results in inappropriate administration of anti-D Ig

A midwife misread the laboratory grouping report and made a verbal request for 1500 iu anti-D Ig following a PSE. The BMS on duty did not check the patient's LIMS record and issued the anti-D Ig, which was subsequently administered to a patient known to be RhD positive.

Case 8

Anti-D Ig administered without checking the patient's blood group

A consultant 'thought that the patient was RhD negative' and prescribed 500 iu anti-D Ig following a PSE. The anti-D Ig was issued from a remote clinical stock and administered. At no point in the process was the blood group report ever checked – it showed clearly that the patient was RhD positive.

Case 9

Manual entry of grouping results onto LIMS results in inappropriate administration of anti-D Ig

A patient was correctly grouped in the laboratory as A RhD positive, but the result was manually entered onto the LIMS as A RhD negative; 1250 iu anti-D Ig was issued on the basis of this result and administered to the patient. The grouping discrepancy was only noted after patient discharge when the laboratory report was being filed in the notes, which already contained reports stating the patient was RhD positive.

Case 10

Mis-filed laboratory reports lead to inappropriate administration of anti-D Ig

A traceability record returned to the laboratory indicated that 250 iu anti-D Ig had been issued by a gynaecology ward from clinical stock to a patient known to be RhD positive. It emerged that a grouping report from an RhD negative patient had been wrongly filed in the notes.

Anti-D Ig given to patients with immune anti-D *n* = 17

Of these 17 reported cases 9 resulted from a primary clinical error and 8 from a laboratory error.

- 13/17 occurred in the hospital setting and 4/17 in the community.
- 4/8 of the laboratory errors involved failure to consider that a strongly positive antibody screen could have been from immune anti-D rather than assuming that it must be prophylactic anti-D.
- 2/8 of the laboratory errors involved failure to consult the patient's computer record prior to issue.
- 2/8 of the laboratory errors involved staff who had inadequate knowledge around the issue of anti-D Ig. One was a non-transfusion BMS who offered poor advice to the clinical team, and the other was an unsupervised medical laboratory assistant (MLA) who issued 1500 iu anti-D Ig for RAADP to a patient known to have immune anti-D.
- 7/9 clinical errors involved issue of anti-D Ig from stocks held in the clinical area, outside of laboratory. control.
- 2/9 clinical errors resulted from a community midwife admitting not reading the laboratory grouping report.

Case 11

Misreading the computer record leads to false assumption and inappropriate issue of anti-D Ig

Anti-D Ig was requested following a miscarriage. A grouping sample was sent, which showed a positive antibody screen, identified as anti-D. The BMS misread the laboratory computer record, which indicated that the patient had received anti-D prophylaxis during a previous pregnancy some four years earlier, assumed it applied to the current pregnancy and proceeded to issue the anti-D Ig.

Case 12

Disregard of instructions results in inappropriate administration of anti-D Ig

500 iu anti-D Ig was issued from clinical stock for a patient known to already have immune anti-D. The lead midwife had written clear instructions in the notes that anti-D Ig was not to be given to this patient under any circumstances.

Anti-D Ig given to mothers of RhD negative infants *n* = 8

Four of these errors originated in the clinical area and 4 in the laboratory. All 8 occurred in the hospital setting.

- 2/4 laboratory errors involved inappropriate issue of anti-D Ig by a lone worker BMS on shift duty.
- 2/4 laboratory errors involved mis-transcription of cord grouping results on manual entry to the LIMS.
- 4/4 clinical errors involved inappropriate issue from stock held in the clinical area: 3 where the laboratory report was not consulted even though it was available, and 1 case where a positive cord direct antiglobulin test (DAT) result was misinterpreted as the RhD group.

Case 13

Manual entry of results onto the laboratory computer system leads to inappropriate administration of anti-D Ig

A cord sample was received and grouped (correctly) by a BMS as AB RhD negative, but during manual entry of the blood group into the laboratory computer the result was mis-transcribed as AB RhD positive. There was no double check of the group entry, and 1500 iu anti-D Ig was subsequently issued on the basis of the computer record.

Case 14

Failure to take account of the laboratory report results in inappropriate administration of anti-D Ig

Twins were born to an RhD negative mother and both were grouped (correctly) as RhD negative. The laboratory report was available on the ward for over 24 hours, but midwives still administered 500 iu anti-D Ig to the mother from stock held in the clinical area.

Anti-D Ig given to the wrong patient *n* = 8

These were exclusively clinical errors, involving failure to identify the correct patient. Of the 8 cases, 7 occurred in the hospital setting and 1 in the community.

Case 15

Bedside check performed in the clinic room

Anti-D Ig had been correctly issued by the laboratory for a named post-natal patient. Two qualified midwives performed the bedside check in the ward clinic room, then one went onto the ward and administered the anti-D Ig to a completely different patient, without any further checks.

Case 16

No checks performed in theatre

Anti-D Ig had been issued for a named patient on a gynaecology theatre list. An anaesthetist administered the anti-D Ig to the wrong patient on the list, without making any ID or blood group checks.

Wrong dose of anti-D Ig given *n* = 12

Four of the 12 errors were by midwives, 6 errors occurred in the laboratory, 1 was an incorrect verbal report by a NHSBT consultant and 1 was an incorrect prescription by a medical officer. Ten cases occurred in hospital and 2 in the community.

Case 17

Incorrect prescription results in inadequate dose of anti-D Ig

The laboratory reported a raised transplacental haemorrhage (TPH) of 13.5 mL, for which a 1750 iu dose of anti-D Ig was indicated. The laboratory issued 1 × 1500 iu, and 1 × 250 iu. The attending medical officer wrote a prescription for only 750 iu, and the midwives administered half of the 1500 iu vial, returning the rest to the laboratory. By the time the mistake was realised, and the rest of the anti-D Ig re-issued and administered, more than 72 hours had elapsed.

Case 18

Use of old laboratory SOP results in excessive administration of anti-D Ig

The laboratory reported a raised TPH of 11 mL, for which a 1375 iu dose of anti-D Ig was indicated. The laboratory SOP contained a table indicating numbers of vials of anti-D Ig required to make up a range of doses. However, this table was based on 1250 iu vials, which were no longer stocked by the laboratory and had been replaced by 1500 iu vials. The SOP had not been updated, and this resulted in the issue of 2 × 1500 iu anti-D Ig when a single vial would have been sufficient.

Case 19

Incorrect verbal report results in excessive administration of anti-D Ig

An NHSBT reference laboratory reported a fetomaternal haemorrhage (FMH) result of 183 mL, requiring 18,300 iu anti-D Ig to be given intravenously (IV). The anti-D Ig was administered by the hospital, but the NHSBT consultant later telephoned to say that the result given was in fact the hospital's own Kleihauer figure submitted to the reference laboratory. The correct FMH result was 130 mL, so the patient had received 5000 iu anti-D Ig more than necessary.

Case 20

Lone worker BMS issued insufficient anti-D Ig

A BMS working a night shift issued 250 iu instead of 500 iu anti-D Ig for a patient with a PV bleed at 22 weeks. Anti-D Ig issue is subject to double checking during normal working hours, but not out of hours.

HSE relating to anti-D Ig *n* = 4

Three of the 4 errors occurred in the clinical area and 1 was a laboratory error. Three errors occurred in a hospital and 1 in the community.

Case 21

Incorrect route of administration

A consultant in theatre administered 250 iu anti-D Ig IV rather than intramuscularly (IM).

Case 22

Incorrect paperwork issued with anti-D Ig

A laboratory issued 3 doses of anti-D Ig for RAADP with the incorrect batch number on all the paperwork. The discrepancy was not noted in the clinical area and the anti-D Ig was administered.

Case 23

Anti-D Ig stored inappropriately on a ward

A patient due to receive anti-D Ig discharged herself before it could be given. The midwives failed to return the unused vial to the laboratory, but kept it in an unspecified location on the ward. It was administered to the patient when she returned 1 month later.

COMMENTARY

The number of cases reported to SHOT under the anti-D Ig category has increased again in 2010. This represents the continuation of an upward trend in reporting since SHOT reporting commenced in 1996 (see Figure 7), and probably indicates an increasing awareness of the need to report rather than a decline in standards of practice.

Recurring themes in the 241 cases analysed this year include the following:

- Patient ID checks are not being performed at all stages of the process.
- There is evidence of incorrect information, misunderstanding and incorrect transcription when results are telephoned, and a robust recording and readback system needs to be in place for both giving and receiving results.
- Transcribing blood grouping results onto care plans or the front of notes is not a secure way of recording results.
- There is a general lack of understanding of the principles around anti-D Ig prophylaxis and the need to still cover sensitising events following RAADP.
- Decision-making regarding issue of anti-D Ig by laboratory staff lacking relevant knowledge and experience.

- Failure to consult the historical group and/or antibody results on the laboratory IT record before issue of anti-D Ig.
- Issue of anti-D Ig outside the relative security of the laboratory IT system.
- Poor advice given by midwives to patients in six cases regarding the need for anti-D Ig following PSEs.
- Clinical staff not reading or misreading laboratory reports before making treatment decisions.
- Inappropriate administration from stocks of anti-D Ig held in the clinical area outside of laboratory control.
- Laboratory reports need to be clearer with respect to the need for anti-D Ig prophylaxis.
- The use of rapid techniques for D typing, which are clearly not robust.
- The inappropriate use of the Kleihauer test to decide whether or not anti-D Ig needs to be given in the first place.

It is pleasing to note from comments made in 3 case analyses that hospitals are beginning to risk-assess the requirement to maintain stocks of anti-D Ig in the clinical area, away from laboratory oversight, but it is still clear that inappropriate issue of anti-D Ig from remote stocks continues to occur.

Engagement between clinical and laboratory areas is still lacking, illustrated by the change in the format of laboratory reports from paper to electronic by one department that resulted in significant problems for midwives generating follow-up appointments, and now necessitates the laboratory producing a separate paper list of patients eligible for RAADP.

Recommendations

- All healthcare professionals involved in the issue and administration of anti-D Ig must complete the anti-D modules in the Learn Blood Transfusion e-learning programme.

  Action: Royal College of Midwives, Royal College of Obstetricians and Gynaecologists, Royal College of General Practitioners

- If there is any doubt as to the true RhD status of a patient, or whether anti-D detected in an antibody screen is of immune or prophylactic origin, and these questions cannot be quickly resolved, then prophylactic anti-D Ig should be administered rather than place the patient at risk by withholding it.

  Action: HTCs

For active recommendations and an update on their progress, please refer to the SHOT website.

11. Acute Transfusion Reactions (ATR)

Definition

Acute transfusion reactions are defined in this report as those occurring at any time up to 24 hours following a transfusion of blood or components, excluding cases of acute reactions due to IBCT, HTR, TRALI, TACO, TAD or those due to bacterial contamination of the component.

DATA SUMMARY

Total number of cases	**510**

Implicated components	
Red cells	**353**
FFP	**45**
Platelets	**95**
Other (granulocyte)	**1**
Multiple components	**14**
Unknown	**2**

Mortality/morbidity	
Deaths due to transfusion	**1**
Deaths *probably/likely* due to transfusion	**0**
Deaths *possibly* due to transfusion	**2**
Major morbidity	**57**

Gender	
Male	**240**
Female	**254**
Not known	**16**

Age	
≥18 years	**451**
16 years to <18 years	**9**
1 year to <16 years	**35**
>28 days to <1 year	**6**
Birth to ≤28 days	**3**
Not known	**6**
Total	**510**

Emergency vs. routine and core hours vs. out of core hours	
Emergency	**86**
Routine	**390**
Not known	**34**
In core hours	**366**
Out of core hours	**126**
Not known	**18**

Where transfusion took place	
A&E	**2**
Theatre	**19**
ITU/NNU/HDU/recovery	**89**
Wards	**337**
Community	**8**
Outpatient/day unit	**35**
Not known	**20**

Introduction

There has been a further 27% increase in the number of reports of ATRs (increased from 400 reports in 2009 to 510 in 2010). The 510 cases reviewed in this chapter are unlikely to represent all ATRs seen in the UK in 2010. The incidence of febrile reactions to pre-storage leucoreduced red cells has been quoted as 0.19%[1,2] and that of allergic reactions to leucoreduced platelets as 2.2%.[3] Personal communications from several reporting hospitals indicate that many reporters choose to include only the more severe reactions. This would be in keeping with the fall in the number of mild cases reported, both in percentage terms and absolute numbers, while the number of reports has increased.

Many of the reports in this chapter may not in fact have resulted from a transfusion reaction as defined in Table 36. The symptoms and signs of ATRs are not unique and may be related to the patient's underlying condition or to other treatments. Classification therefore tends to be subjective. Nevertheless, it is worthwhile recording the clinical features, management and investigation of all cases in which the presentation led to reporters identifying possible transfusion reactions, in order to promote best practice.

Figure 8
ATR cases 1996–2010

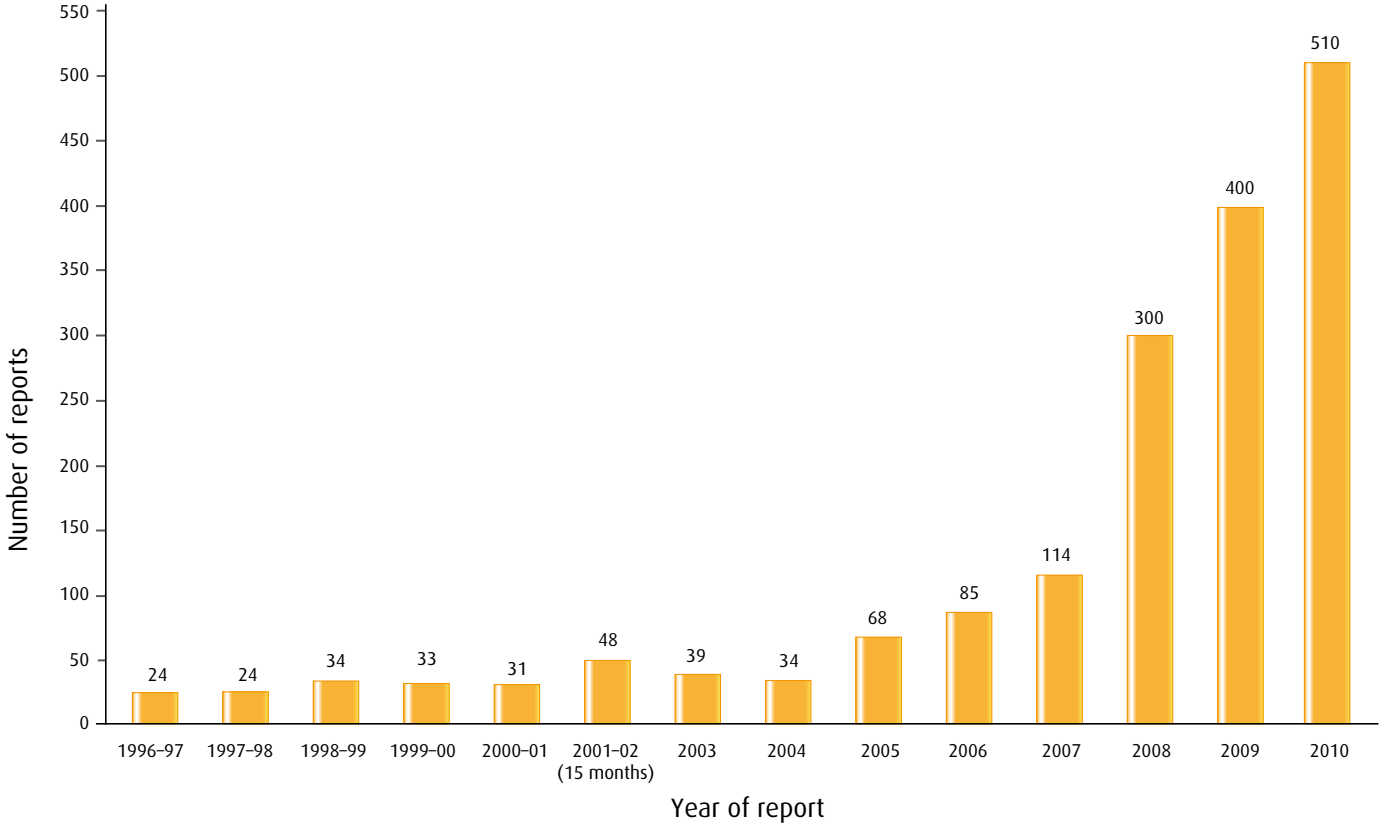


Table 36
Draft BCSH classification of ATRs

Category	1 = Mild	2 = Moderate	3 = Severe
Febrile type reaction	A rise in temperature up to 2°C with no other symptoms/signs	A rise in temperature of 2°C or more, and/or rigors, chills, other inflammatory symptoms/signs such as myalgia, hypotension or nausea, which precipitate stopping the transfusion	A rise in temperature of 2°C or more, and/or rigors, chills and other inflammatory symptoms/signs such as myalgia, hypotension or nausea that precipitate stopping the transfusion, prompt medical review AND/OR directly result in or prolongs hospital stay
Allergic-type reaction	Transient flushing, urticaria or rash	Wheeze or angioedema with or without flushing/urticaria/rash but without respiratory compromise or hypotension	Bronchospasm, stridor, angioedema or circulatory problems that require urgent medical intervention AND/OR directly result in or prolong hospital stay, or **anaphylaxis** (severe, life-threatening, generalised or systemic hypersensitivity reaction with rapidly developing airway and/or breathing and/or circulation problems, usually associated with skin and mucosal changes[4])
Reaction with both allergic and febrile features	Features of mild febrile **and** mild allergic reactions	Features of both allergic and febrile reactions, at least one of which is in the moderate category	Features of both allergic and febrile reactions, at least one of which is in the severe category
Hypotensive reaction		Isolated fall in systolic or diastolic pressure of 30 mm or more[5] in the absence of allergic or anaphylactic symptoms No/minor intervention required	Hypotension leading to shock (e.g. acidaemia, impairment of vital organ function) without allergic or inflammatory symptoms Urgent medical intervention required

The classification of ATRs can be problematic, as reactions are frequently seen in patients with intercurrent illness who may have other causes for their symptoms. Classification does not necessarily have any bearing on the management of the acute reaction or of future transfusions.

In addition to the SHOT classification of ATRs by death or major morbidity, it has been noted that the International Society for Blood Transfusion (ISBT) and the International Haemovigilance Network (IHN) are developing standard definitions for non-infectious ATRs in order to help haemovigilance organisations generate data that will be comparable at an international level. In the meantime, the above definitions have been put forward by the writing group of the forthcoming BCSH guideline on the investigation and management of ATRs. The SHOT annual report has therefore also shown ATRs according to this classification.

Types of reactions

As far as possible, reactions have been classified and the following figures obtained:

- 283 febrile
- 122 allergic
- 34 anaphylactic
- 27 mixed allergic/febrile
- 19 hypotensive
- 25 unclassifiable.

The data in Figure 9 show that reports of febrile reactions are less common with plasma than with red cell or platelet transfusions, and that allergic reactions are much more frequent with plasma-rich components. The incidence by component type is summarised in Table 37.

Figure 9
Reaction by component type *(excluding 6 reactions that could not be attributed to a particular component)*

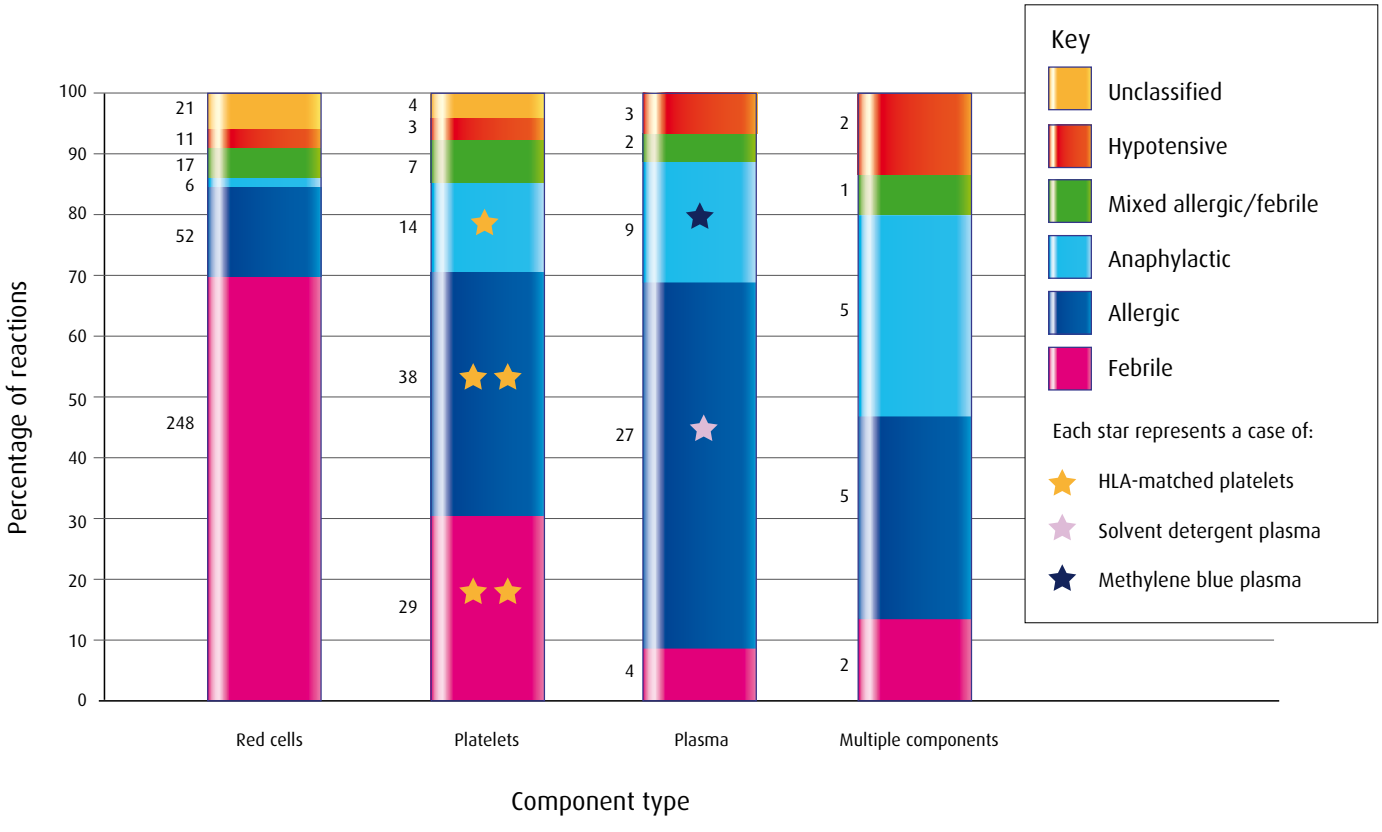


Table 37
Incidence of reactions by component type

Component	Febrile reactions, incidence per 100,000 units	Allergic or anaphylactic reactions, incidence per 100,000 units
Red cells	11.2	2.4
Platelets	10.5	13.8
Plasma	0.9	6.4
SD-FFP	0.0	0.17

Five reactions were reported with HLA-matched platelets, all from England, where 14,174 HLA-matched platelets were issued in 2010, therefore giving an incidence of 35 per 100,000.

Deaths

Although death occurred at around the time of, or shortly after, transfusion in 21 cases, in all but 3 the reporter concluded the reaction was not implicated. The majority of these patients had severe intercurrent illness or were very frail.

Case 1
Death stated to be solely attributed to transfusion reaction (imputability 3)
An elderly patient was found to be unconscious and not breathing 4 hours into the first unit of a red cell transfusion for anaemia of unknown cause. Resuscitation was unsuccessful. A post-mortem mast cell tryptase (MCT), taken several days later, was stated to be markedly raised. Unit cultures were negative. It was concluded that the patient had died of anaphylaxis due to the transfusion.

A review of post-mortem findings in deaths due to anaphylaxis, none of which was related to transfusions, found that 23/56 cases had no signs indicative of allergy.[6] Of the 16 cases that had MCT measured, 14 had raised levels. The review concludes that physical and laboratory findings must be considered along with the clinical history. This case has been included in the anaphylactic section.

Two cases are included on the website (www.shotuk.org) in which the possibility that a transfusion reaction contributed to a patient's death could not be excluded.

Major morbidity *n* = 57

Applying the criterion of 'life-threatening acute reaction requiring immediate medical intervention', there were 57 reports in which a transfusion reaction had symptoms or signs that were sufficiently severe to imply that delay in treatment could be life-threatening. However, in 4 cases of hypotension this may equally have been due to underlying bleeding or sepsis. The remaining 53 cases included 34 anaphylactic and 1 angioedema reaction, 11 allergic reactions with bronchospasm, 6 severe hypotensive reactions (including 2 cases of transfusion associated with the onset of arrhythmias) and 1 supraventricular tachycardia with a fever.

Case 2

Anaphylaxis during FFP

An elderly male patient received the first unit of FFP to correct a coagulopathy. Half-way through the unit, he developed marked hypotension (from 100/60 to 50/20) and a widespread urticarial rash and shortness of breath (SOB). He recovered following treatment for anaphylaxis and subsequently received the second unit of FFP uneventfully.

Cases 3 and 4 illustrate the difficulty in determining whether a reaction is due to transfusion or the patient's underlying condition, which was the conclusion in these two cases.

Case 3

Hypotension due to red cells or bleeding?

A male child undergoing surgery developed a marked tachycardia and hypotension 45 minutes into transfusion of red cells, after 300 mL had been given, but because of ongoing bleeding, transfusion could not be withheld while investigations were undertaken. MCT was normal and bacterial cultures of the unit were negative.

Case 4

Apparent FFP-related anaphylaxis, twice on starting FFP

An adult male patient underwent cardiothoracic surgery and received red cells and 1 unit of FFP without problems. However, 1 minute into the second unit of FFP, his blood pressure (BP) dropped from normal to unrecordable with anaphylaxis. He recovered after adrenaline, hydrocortisone and antihistamine were given. Later, a further unit of FFP resulted in the same reaction after just a few minutes, as witnessed by the same consultant anaesthetist. IgA levels were normal. No other causes of anaphylaxis (e.g. drugs) were identified. A few days later, the patient returned to theatre and, following surgery, a further similar anaphylactic episode occurred, this time without recovery. However, on this occasion, no blood components had been given within the preceding 24 hours, therefore, on review, transfusion was unlikely to have been the cause of the first two episodes of anaphylaxis.

Learning point

- In the acute situation, it can be difficult to determine whether new adverse clinical features are due to an ATR, to other complications of transfusion or to the patient's illness. The over-riding priority is to manage the clinical condition, whether or not the cause is clear.

Severity of reactions

Of the 485 reactions that could be classified, 59 (12.2%) were considered to be severe, 346 (71.3%) moderate and 80 (16.5%) mild. The comparable figures for 374 classifiable reactions in 2009 were 12.1%, 52.6% and 35.3%, respectively. This may represent a change in reporting practice, with fewer mild reactions being reported.

Severe reactions

Although ATRs are rarely associated with death or long-term morbidity, they may present with severe symptoms in the acute situation. Of the 59 severe reactions, 57 were the life-threatening reactions in the section on major morbidity and a further 2 were febrile, causing prompt medical review and prolonged hospital stay: 1 was a fever of 40ºC in a 1-year-old child and 1 was a FNHTR with vomiting in a 79-year-old. Reactions can present in any patient, irrespective of whether they have experienced reactions previously. This highlights the need for patients to be transfused where there are adequate resources for managing acute reactions, particularly anaphylaxis. This also applies to transfusions carried out in community hospitals or at home. Additional vignettes of severe reactions are available on the SHOT website.

Anaphylactic reactions

This year, 34 reactions with features suggestive of anaphylaxis were reported, including a fatality, as described above. Additional vignettes are available on the website.

Six reports were related to red cell transfusions, 9 to plasma, 14 to platelets (including 1 with an HLA-matched platelet) and 4 to multiple transfusions. As in 2009, the mean time to onset was shorter than for other reactions at 26 minutes. The reaction occurred during the transfusion in 15/34 cases. In 22 cases it was thought to have certain or probable imputability (65%) compared to 172/510 of the total number of reactions (34%).

Case 5

Anaphylactic reaction to MB-FFP

A young female patient was transfused with MB-FFP to correct a coagulation abnormality prior to surgery. She developed a rash and angioedema, as well as some lumbar pain and rigors, and required treatment with 2 doses of IM adrenaline, steroids, antihistamine and inotropes. She required overnight admission to the HDU but recovered within 24 hours.

Symptoms and signs

Hypotension was reported in all but 7 cases, and in 15/33 this was recorded as a drop of over 30 mm of systolic or diastolic blood pressure. The 7 cases in which hypotension was not mentioned included 3 in which a rash was associated with malaise of rapid onset and vomiting, 2 which the reporting team stated were anaphylaxis, 1 who sustained a cardiac arrest and the patient in whom death was attributed solely to an anaphylactic transfusion reaction. The most common combination of signs was hypotension and rash (13 cases).

Case 6

Collapse of unknown cause

A female patient in her 60s with leukaemia received a unit of apheresis platelets as a day case, for prophylaxis. Hydrocortisone and chlorpheniramine were given prior to transfusion. She developed a rash, initially on her arm then spreading further. She was given more chlorpheniramine and then lost consciousness. The cardiac arrest team were called. Fluids were given, as well as more hydrocortisone, and the patient recovered. MCT was slightly raised, but no baseline sample was performed. A decision was made to use washed platelets for future transfusions. Intravenous chlorpheniramine can lead to transient hypotension, particularly in older patients.

Management

Despite the severity of most of these reactions, only 2 patients required transfer to ITU and 1 day case required admission. In 1 case the cardiac arrest team was called but the patient recovered within 1 hour. Only 13 patients were treated with adrenaline, the recommended first-line therapy.

Learning point

- It is worth repeating that the UK Resuscitation Council (UKRC) recommends that IM adrenaline is the first-line treatment for anaphylaxis of whatever cause.[4]

Severe febrile reactions

There were 33 severe febrile reactions: 27 of these were related to red cell transfusions, 5 to platelets and 1 to red cells and platelets. Two cases required transfer to ITU, and in 22 day-case patients the reaction led to an overnight stay. The other cases were classified as severe as they required immediate clinical intervention. Two patients died, of unrelated causes. Three patients had sepsis at the time of the reaction, with positive blood cultures likely to be due to underlying infection rather than to TTI.

Case 7

Severe febrile reaction

A young female patient with acute myeloid leukaemia experienced violent shaking, cyanosis, nausea, tachycardia and a slight rise in temperature during a transfusion of apheresis platelets, which were being given prophylactically as her platelet count was <10. She had experienced a similar, milder reaction 3 days previously. She was managed with paracetamol. Patient and unit cultures were not performed.

Hypotensive reactions

There were 18 reactions involving severe falls in blood pressure, and in 14 of these cases the reporting team stated that hypotension was the predominant clinical feature. It is worth noting that 7/18 of these reactions occurred in the operating theatre (39%) as compared to 19 of the 510 total acute reactions reported (4%). Of the reactions outside theatre, 3 were described in patients having major bleeds and 2 were in postoperative patients.

Risk factors for hypotensive reactions include exposure of the blood to negatively charged filters, prostatic surgery, cardiac procedures involving bypass, use of angiotensin converting enzyme (ACE) inhibitors and patient factors such as a defect in kinin metabolism.[7] However, in several of the current reports, given the clinical setting, the possibility that haemorrhage contributed to the hypotension could not be excluded.

Moderate/mild reactions

The remaining moderate and mild reactions included many febrile non-haemolytic transfusion reactions (FNHTRs) or fevers only; however, a number of these required precautionary admission, e.g. in immunosuppressed haematology patients (11) or elderly patients living alone (3). A further 3 patients with an allergic rash alone required admission following transfusion in community hospital or hospice settings. Although not severe in terms of symptoms and signs, such reactions can have implications for management in susceptible patients.

Reactions that were not possible to classify further

There are 25 cases included in this chapter in which the HTTs, using the information present at the time, decided that a diagnosis of ATR was most likely. Further attempts to classify these reactions were not pursued, as management of the patient, and exclusion of other potentially serious causes of the symptoms, should be the main priority of the clinical team, and are not dependent on classification of the reaction type. The following case illustrates some of the diagnostic difficulties that can be encountered.

Case 8

Imputability unknown

An elderly female patient was admitted with probable pneumonia and severe iron deficiency. She was transfused 3 units of red cells. During the third unit, she became more dyspnoeic, with oxygen saturation of 88%, and her BP dropped to 86/44 mm. Imputability was given as unlikely, and the possibility of symptoms being related to the underlying condition, or to TACO, cannot be ruled out.

Investigations

The value of investigations in ATR was discussed in the 2008 SHOT annual report. In 2010:

- 27 cases had HLA antibodies performed, with antibodies demonstrated in 7 cases – none of these results was recorded as leading to the use of HLA-matched components
- 20 cases had HPA antibodies performed and in 1 case antibodies were found but did not influence future component choice.

It is worth reiterating that HLA, HPA or human neutrophil antigen (HNA) investigations of the patient should only be performed after discussion with a Blood Service consultant. The primary indication for HLA testing should be platelet refractoriness, with or without evidence of a transfusion reaction.[8]

- IgA levels were measured in 62 patients and low levels were detected in 2 cases: 1 with an allergic reaction and 1 with a febrile reaction. In neither of these cases did the result appear to influence the choice of future components.

The significance of IgA levels does not appear to be as great as has been previously stressed, especially as the incidence of IgA deficiency is said to be approximately 1 in 700 of the UK population and therefore present in many transfusion recipients who do not experience reactions.[9] Nevertheless, as it has been considered to play an important role in the aetiology of anaphylaxis in the past, it is recommended that levels should be checked in cases of severe allergic or anaphylactic transfusion reactions as IgA deficiency may be part of the spectrum of common variable immunodeficiency.

Table 38
Summary of investigations for suspected ATRs

Mild febrile reaction (isolated pyrexia, otherwise no change in symptoms/signs) or mild allergic reaction (rash/itch)	No tests required
Features of anaphylaxis/angioedema, other severe allergy	■ Test for IgA deficiency; if present test for anti-IgA antibodies ■ Consider causes other than blood components ■ Serial MCT tests may subsequently confirm diagnosis
Fever with any of: increased heart rate (HR), decreased blood pressure, increased respiratory rate (RR)	If not clearly severe allergic/anaphylactic reaction, consider: ■ checking for 'wrong blood'; if indicated, perform G&S, DAT (G&S and DAT investigations should not be done universally in all ATRs, but are indicated as above or in the presence of haemoglobinuria, loin pain or venous pain at the cannula site) If symptoms are severe, consider: ■ bacterial contamination of blood component; blood cultures from patient; notify Blood Service (for consideration of other components from donor) and culture unit(s)
Shortness of breath	■ If not associated with anaphylaxis, consider TAD, TACO, TRALI and causes unrelated to blood components ■ Pulse oximetry/blood gases ■ CXR

COMMENTARY

The number of ATRs reported has increased further this year, mainly because of the increased numbers of febrile or allergic reactions reported. The number of anaphylactic reactions has stayed fairly constant over the last 3 years. Mild reactions have reduced, both in percentage terms and absolute numbers.

Several cases initially reported as ATRs have been transferred into the TAD section. Differentiation between ATR and TAD is difficult and it would be helpful, where possible, to know which clinical feature predominated in the reaction, as respiratory symptoms may point to TAD.

This year, hypotensive reactions appear to have increased. Many reports are of patients undergoing major surgery or who are bleeding. This highlights the inherent difficulties in making a diagnosis of a transfusion reaction. Risk factors said to contribute to hypotensive reactions include exposure of blood to negatively charged surfaces such as bedside filters, ACE-inhibition[10] and genetic predisposition. However, careful assessment of a presumed hypotensive reaction is required, for example in patients who are bleeding in whom the hypotension may be caused by haemorrhage, in which case continuation of the transfusion may be life saving.

Recommendation

- Transfusions should only be performed where there are facilities to recognise and treat anaphylaxis, according to UK Resuscitation Council (UKRC) guidelines. In supplying to community hospitals or for home transfusions, providers must ensure that staff caring for patients have the competency and facilites to deal with this adverse reaction.[4]

  Action: HTCs

For active recommendations and an update on their progress, please refer to the SHOT website.

12. Haemolytic Transfusion Reactions (HTR)

Definition

Haemolytic transfusion reactions are split into two categories: acute and delayed.

- Acute reactions are defined as fever and other symptoms/signs of haemolysis within 24 hours of transfusion, confirmed by one or more of a fall in Hb, a rise in lactate dehydrogenase (LDH), positive DAT and positive crossmatch.
- Delayed reactions are defined as fever and other symptoms/signs of haemolysis more than 24 hours after transfusion, confirmed by one or more of a fall in Hb or failure of increment, a rise in bilirubin, positive DAT and positive crossmatch which was not detectable pre-transfusion.
- Simple serological reactions (development of antibody without positive DAT or evidence of haemolysis) are excluded.

DATA SUMMARY

Total number of cases	**58**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**58**	Deaths due to transfusion	**1**
		FFP	**0**	Deaths *probably/likely* due to transfusion	**0**
		Platelets	**0**	Deaths *possibly* due to transfusion	**0**
		Other (granulocyte)	**0**	Major morbidity	**2**
		Unknown	**0**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**19**	≥18 years	**57**	Emergency	**13**	A&E	**2**
Female	**38**	16 years to <18 years	**0**	Routine	**43**	Theatre	**9**
Not known	**1**	1 year to <16 years	**1**	Not known	**2**	ITU/NNU/HDU/recovery	**7**
		>28 days to <1 year	**0**				
		Birth to ≤28 days	**0**	In core hours	**45**	Wards	**36**
		Not known	**0**	Out of core hours	**9**	Community	**0**
		Total	**58**	Not known	**4**	Outpatient/day unit	**3**
						Not known	**1**

Alloimmunisation

This is the first year that SHOT has collected data from cases in the category of alloimmunisation.

Definition

Alloimmunisation occurs when, after a transfusion, there is demonstration of clinically significant antibodies against RBCs that were previously absent (as far as is known) and when there are no clinical or laboratory signs of haemolysis. This term is categorised as a delayed serological transfusion reaction (DSTR) by the ISBT.

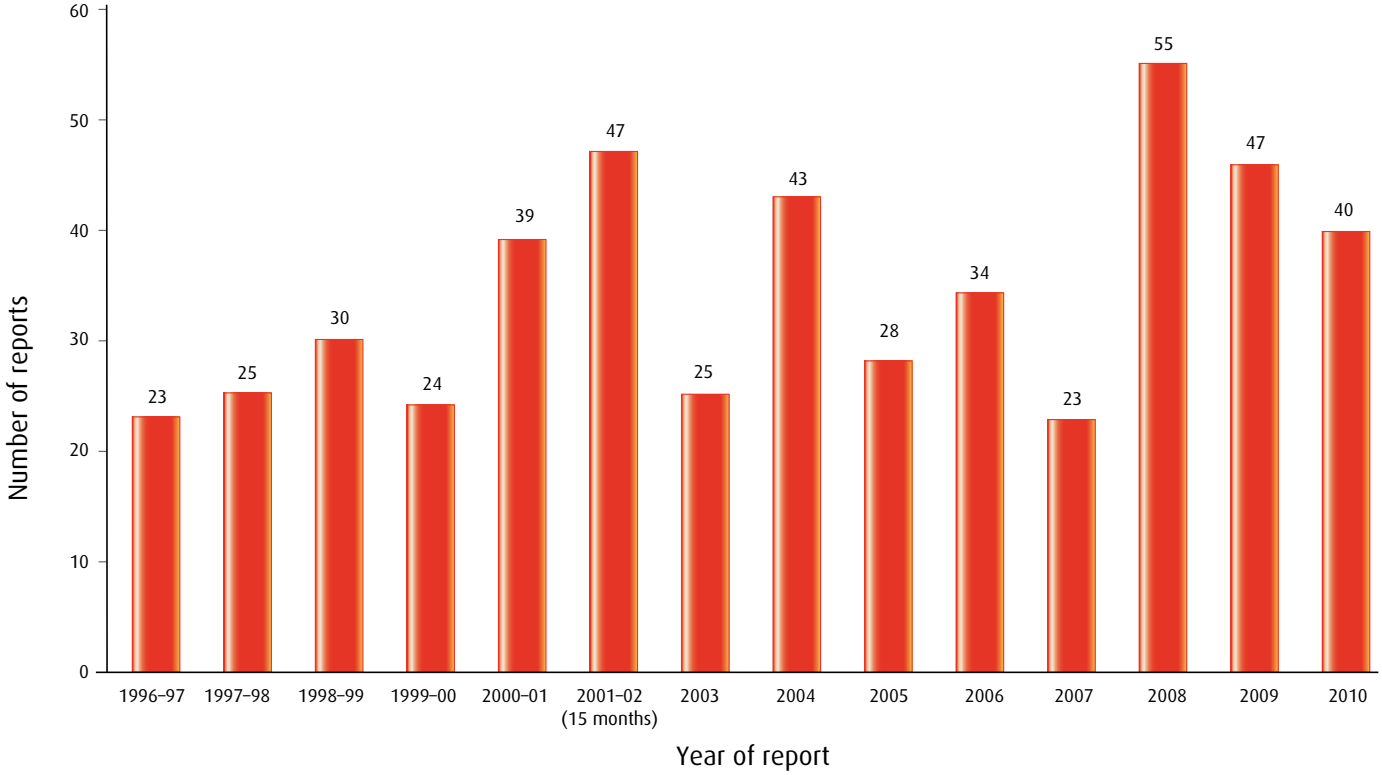
Development of an antibody with positive DAT or development of haemolysis should be reported in the HTR category.

A minimum data set is collected, but it was clear from the descriptions given that at least some of the cases reported as alloimmunisation had positive DATs and would currently fall into the SHOT definition of DHTR. For this reason the two categories of DHTR and alloimmunisation have been combined for this year's report. All 18 cases reported as alloimmunisation, plus a further 7 cases reported as DHTR with no clinical or laboratory signs of haemolysis, are summarised in Table 41.

Haemolytic transfusion reactions

There were a further 27 cases reported as DHTRs and 6 as AHTRs, giving a total of 58 cases in this chapter.

Figure 10
Number of cases of HTR reviewed since 1996



NB The graph does not include the 18 cases of alloimmunisation reported in 2010.

Mortality and morbidity

Acute haemolytic transfusion reactions (AHTR) *n* = 6

A paediatric patient with sickle cell disease died as a direct result of hyperhaemolysis following transfusion (imputability 3). The hyperhaemolysis episode was noted 13 days post transfusion and was exacerbated by a further transfusion. The remaining 5 cases of AHTR suffered minor morbidity only.

Case 1

Death due to hyperhaemolysis

A paediatric patient with sickle cell disease had an Hb of 8.1 g/dL and received 1 unit transfusion prior to a tonsillectomy. Thirteen days later she was admitted unwell with an Hb of 5.4 g/dL. Following a further 2 units of red cells, she deteriorated and her repeat Hb was 4.8 g/dL. She was transferred to a paediatric ITU at a specialist centre, but on arrival through A&E received a unit of flying squad group O RhD negative red cells. Hyperhaemolysis was suspected and she received IVIg and methylprednisolone. Although her Hb was initially 6.6 g/dL following receipt of the unit of flying squad, within 6 hours it had fallen to 3.8 g/dL and she had developed multi-organ failure (MOF) and acute respiratory distress syndrome (ARDS). The patient died the same day.

Learning point

- Hyperhaemolysis is an uncommon but well-documented serious complication of transfusion in sickle cell disease in which there is destruction of both autologous and transfused red cells. If possible, further transfusion should be avoided since this may exacerbate the haemolysis and lead to a protracted course or even death. The use of IVIg and/or steroids should be considered as a means of correcting the anaemia.

Delayed haemolytic transfusion reactions (DHTRs), including alloimmunisation *n* = 52

Two cases met the definition of major morbidity: 1 required admission to HDU 5 days post transfusion and another had impaired renal function 12 days post transfusion. Both reactions were clearly related to the transfusion and both patients made full recoveries.

The remaining 25 cases of DHTR suffered minor morbidity only. A further 25 cases, including those reported in the alloimmunisation category, had no clinical or laboratory signs of haemolysis, except for a positive DAT in some cases.

Timing of reaction in relation to the transfusion

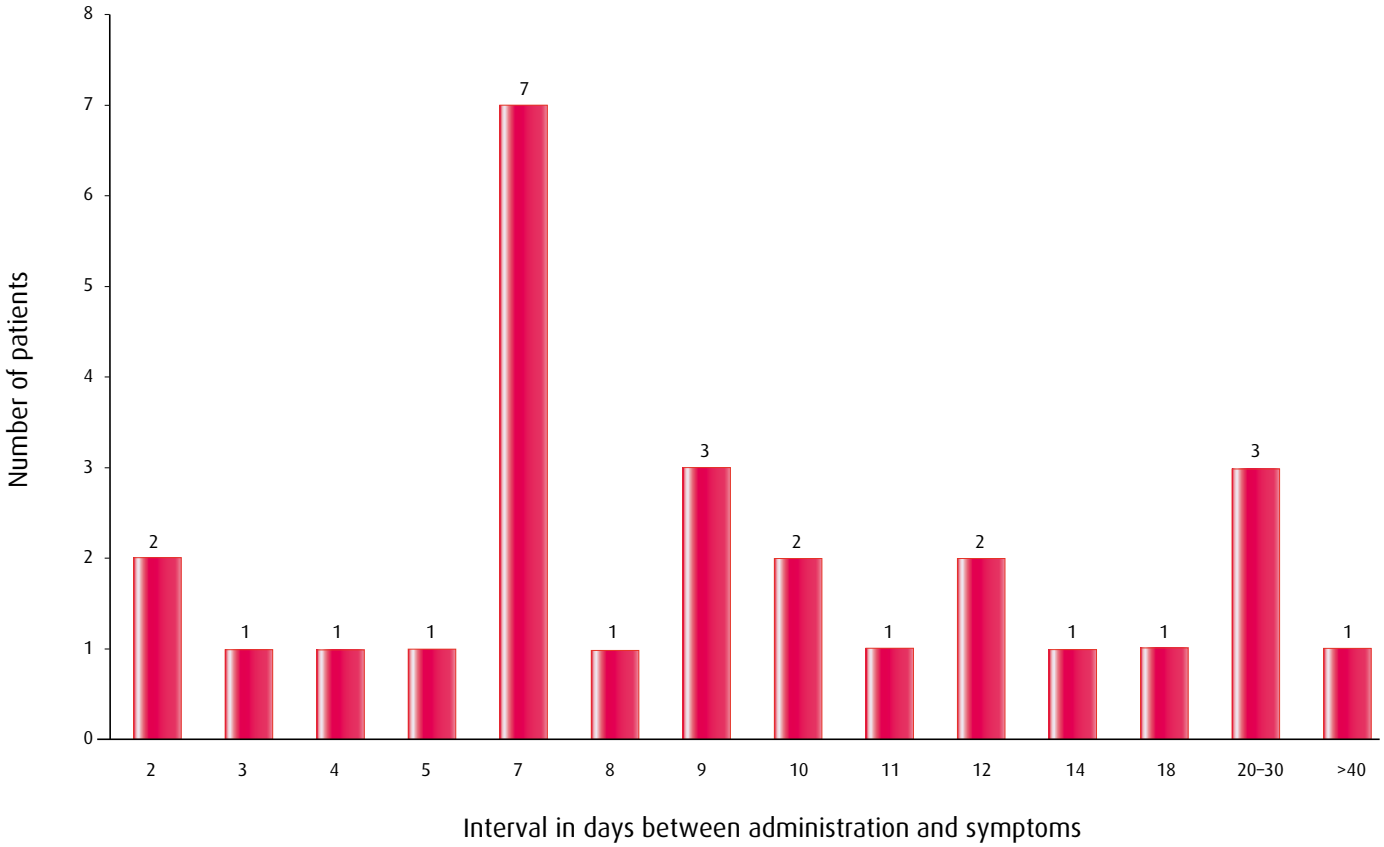
AHTR

Excluding the patient who died due to hyperhaemolysis, 4 of the reactions occurred during the transfusion, which was stopped on the advice of a doctor, and 1 occurred shortly after the transfusion was finished.

DHTR

Figure 11 shows the reported interval in days between the implicated transfusion and the clinical signs of a DHTR. The median time interval was 9 days, with a range of 2 to 41. New antibodies were found between 4 days and 3 months after transfusion in the 25 asymptomatic cases.

Figure 11
Interval in days between administration of the implicated transfusion and signs or symptoms of a DHTR



Serological findings – AHTR *n* = 6

This year no reactions were reported due to ABO incompatible platelet transfusion – all reactions were associated with red cell transfusions.

No alloantibodies were detected in the plasma of the patient who died following hyperhaemolysis. Anti-Jk^{a} was associated in 2 cases, including 1 where it was only detectable post transfusion in an eluate. In 1 case, an antibody to a low frequency antigen was suspected, in another anti-Co^{b} was missed in the IAT crossmatch and in the last case no specificity was assigned.

Case 2

Reaction possibly due to an antibody to a low frequency antigen

A patient was being transfused following a PPH. The transfusion was stopped when the patient showed signs of fever, chills, rigors and tachycardia. There was no evidence of haemolysis. However, the implicated unit (originally released by EI), was found to be incompatible on retrospective crossmatch; the antibody screen, DAT and eluate were all negative, and an antibody to a low frequency antigen was suspected.

Case 3

Reaction possibly due to enzyme-only anti-Jk^{a}

The patient twice spiked a temperature during a transfusion for chronic anaemia before it was stopped. Anti-Jk^{a} was detected retrospectively in the pre-transfusion sample by enzyme technique only, and the unit was confirmed as Jk(a+); the DAT was positive pre and post transfusion, but an eluate was non-reactive and there was no evidence of haemolysis.

These two cases demonstrate how difficult it is to classify ATRs where antibodies are detected retrospectively, but the transfusion is stopped early and no evidence of haemolysis is noted. It is not possible to be sure whether the antibodies are the cause of the reaction or coincidentally present.

Case 4

Anti-Jk^{a} only detectable in an eluate

A patient suffered fever and rigors and became hypertensive shortly after a transfusion for chronic anaemia. The post-transfusion DAT was positive and anti-Jk^{a} was detected in an eluate made from the patient's red cells but not in the plasma. The Hb fell back to the pre-transfusion level within 4 days of the transfusion.

Case 5

Anti-Co^{b} missed in crossmatch

A patient requiring transfusion for chronic anaemia had anti-E, anti-Co^{b} and an autoantibody, plus previously detected anti-Jk^{a}, -C^{w} and -Lu^{a}. The Blood Service provided 3 units of crossmatch compatible E-, C^{w} -, Jk(a-) red cells. During transfusion of the second unit, the patient had dyspnoea, headache and chills, and the transfusion was stopped; subsequently, signs of haemolysis were noted, including a fall in Hb and a raised bilirubin. Retrospective testing found 2 of the 3 units to be Co(b+) and incompatible in the IAT crossmatch. Policy at the time was to issue crossmatch compatible units rather than Co^{b} type, due to limited availability of a Co^{b} typing reagent. Anti-Co^{b} reagent was actually available at the time and the policy has since been changed to phenotype units for Co^{b} whenever possible.

Case 6

No specificity identified

A patient with anti-D, -C, -E, -K, -Jk^{a} and -M was provided with 3 units of antigen negative, crossmatch compatible red cells for chronic anaemia. During the third unit, the patient suffered fever, back pain and vomiting, and the transfusion was stopped; subsequently signs of haemolysis were noted, including a fall in Hb and a raised bilirubin. Retrospective crossmatching gave the same result, and an eluate gave weak non-specific reactions. The International Blood Group Reference Laboratory (IBGRL) confirmed the antibodies previously identified, plus further positive reactions, with no specificity assigned.

Learning point

- If a typing reagent is available, antigen-negative units should be provided for patients with anti-Co^{b}, since serological crossmatching is more prone to error.

Serological findings – DHTR

A total of 44 new antibodies were identified in 27 patients. Kidd and Rh alloantibodies were again the most common, present in 15/27 (56%) and 13/27 (48%) cases, respectively. Multiple specificities were identified in 43% of cases.

Table 39
Serology, laboratory signs and timing of reaction

Case number*	New antibody (ies) in plasma	Antibodies in eluate	Comments	Days post transfusion
1	M+S+?	Not done	Dark urine; jaundice; Hb↓; bilirubin↑; known anti-c	8
2	Jk^{a}	Jk^{a}, M	Poor/absent increment in Hb; spherocytes	7
3	E, Jk^{a}	DAT negative; no eluate	Fever; headache; patient 'felt off'; bilirubin↑; Hb↓	16
4	C+Jk^{b}	DAT positive C3; no eluate	Bilirubin↑; Hb↓; LDH↑; haemoglobinuria; known anti-E+S DHTR followed by AHTR	14
5	E+K+Jk^{b}	Not done	Hb↓; bilirubin↑↑	9
6	Jk^{a}	Jk^{a}	Hb↓; DAT positive IgG+C3	7
7	K+E+ enz-only c	Not done	Hb↓ but chronic anaemia; bilirubin rising but still normal	41
8	E	Not done	Hb↓; spherocytes	27
9	E	Not done	Hb↓↓; bilirubin↑↑	25
10	E	Not done	Hb↓	20
11	Jk^{b}	Not done	Hb↓; bilirubin↑↑; haemoglobinuria; SCD with known anti-Jk^{b} from 2003 from another hospital	7
12	E+Lu^{b}+auto	E+Lu^{b}+auto	Hb↓↓; bilirubin↑↑; spherocytes; fever, chest pain	10
13	Jk^{a} +Lu^{a}	Not done	Hb↓; bilirubin↑	14
14	Fy^{a}	Fy^{a}	Known anti-E+K; Hb↓	5–7
15	E+c+Fy^{a}	Not done	DAT positive pre and post transfusion Hb↓, but chronic anaemia	11
16	Jk^{a}	Not done	Hb↓; bilirubin↑; creatinine↑	12
17	Jk^{a} + E	Not done	Hb↓; bilirubin↑; LDH↑	7
18	E	Not done	No Hb increment	4
19	Jk^{a}	Not done	Slight rise in bilirubin; death unrelated	4 or 10
20	Jk^{a}	Jk^{a}	Hb↓	10
21	Jk^{b} + Fy^{b}	Auto anti-C	Hb↓; bilirubin↑; dark urine; spherocytes; known anti-c+M	9
22	D	D	Poor Hb increment; spherocytes	7
23	Jk^{a}	Not done	Hb↓; bilirubin↑	7
24	S, Fy^{a}, N, ?	S+ Fy^{a}	Hb↓↓; bilirubin↑↑; haemoglobinaemia; admitted to HDU; known anti-E+Cw+K+Lea+?	5–9
25	Jk^{a} + Fy^{a}	Jk^{a} + Fy^{a}	Hb↓; bilirubin↑; spherocytes	3
26	E	E	Hb↓ but acute bleeding	11
27	Jk^{b}	Not done	Hb↓; bilirubin↑; haemoglobinaemia; spherocytes	10

The case numbers in this table do not correspond to those used in the case studies.
SCD, sickle cell disease.

Table 40
Summary of the cases by antibody specificity

Antibody specificity by blood group system	No. of cases	Sole new antibody
Kidd		
Jk^a	10	5
Jk^b	5	3
Rh		
D	1	1
C	1	0
E	11	5
c	2	0
Kell		
K	2	0
Duffy		
Fy^a	4	1
Fy^b	1	0
MNSs		
M	2*	0
N	1	0
S	2	0
Other		
Lu^a	1	0
Lu^b	1	0
Total	**44**	**15**

** One example of anti-M identifed in eluate only.*

There were 35 cases showing no evidence of haemolysis, 7 reported as DHTR and 15 as alloimmunisation. These cases are summarised in Table 41.

Table 41
New antibodies with or without positive DAT but no clinical or laboratory signs of haemolysis

Specificity	No. of cases
K	3
Jk^a	7
Jk^b	3
Fy^b	1
Lu^a	1
M	2
D	1
E	2
c	2
C+D+E	1
$C+Jk^a+S$	1
$K+Jk^a$	1

Direct antiglobulin tests (DATs), use of eluates and referral to a Blood Service reference laboratory

The DAT was positive in 24 cases and negative in 1; 12 went on to test an eluate, including 1 who stated that a DAT had not been undertaken. Although 8 reporters did not answer either question, this appears to represent a decrease from last year in the number of investigations that included an eluate. Antibody identification was undertaken or confirmed by a reference laboratory in 20/34 cases and it is possible that additional testing, including an eluate, was undertaken by the reference laboratory without the reporter being aware. In 2 cases, 1 acute and 1 delayed, an antibody was only detectable in the eluate.

Learning point

- Testing an eluate is an important part of investigating an HTR, and may be the only way of identifying any or all of the antibodies present.

Case 7

A classic DHTR followed by a preventable AHTR

A patient with anti-E+S required a 2-unit red cell transfusion perioperatively. Fourteen days later, the Hb had fallen by 2 g/dL, the bilirubin had risen from 6 to 26 and the LDH had risen from 294 to 4590. A panel showed anti-E+S plus a further unidentified antibody; the DAT was negative. Two units of E-S- crossmatch compatible red cells were given. During the second unit, 'blood' was noted in the catheter bag and the transfusion was stopped. Anti-Jk^{b} was identified using a different panel and a review showed that this specificity could not be excluded in the pre-transfusion panel. Samples tested 2 days later by a reference laboratory confirmed a weakly positive DAT and the presence of anti-C and -Jk^{b} in addition to E+S; both units were confirmed as C+, Jk(b+). Although the transfusion was stopped, there was no clinical or laboratory evidence of haemolysis, apart from the 'blood' in the catheter bag.

This appears to be a case of classic DHTR possibly followed by an AHTR, the latter being preventable. The laboratory has changed its protocol relating to antibody identification and now refers samples to the Blood Service reference laboratory if antibodies cannot be excluded.

Learning point

- Systematic exclusion of all antibodies of likely clinical significance is an essential part of the antibody identification process and may necessitate the use of further red cells or techniques.

Case 8

Symptoms of DHTR attributed to sickle cell crisis

A patient with HbSC was transfused 2 units of red cells post emergency Caesarean section. Ten days later she presented with an Hb of 6.7 g/dL, fever, hypoxia and pain due to presumed sickle cell crisis. The patient underwent an exchange transfusion (ET) of 6 units of red cells but still had fever, pain and dyspnoea, causing her Hb to drop below pre-transfusion levels and with evidence of haemolysis noted on a blood film. A transfusion reaction investigation was not undertaken until several days later because all the symptoms were attributed to sickle cell crisis. The DAT was positive with anti-Jk^{a} detectable in the eluate on the pre- and post-exchange samples. Four out of the 6 units used for the ET were Jk(a+). The anti-Jk^{a} became detectable in the plasma after a couple of days.

Had this been diagnosed as a DHTR sooner, the 6-unit exchange may have been unnecessary and any red cells transfused could have been typed for Jk^{a}.

Learning point

- A DHTR should be considered as a diagnosis in patients with sickle cell disease presenting with crisis up to 14 days post transfusion.

Case 9

A known antibody from a different hospital, no longer detectable, causes a DHTR

Seven days after a 6-unit ET, a patient with sickle cell disease had a falling Hb, a rising bilirubin and haemoglobinuria. The DAT was positive and anti-Jk^b was identified in the plasma; however, an eluate was not tested. Subsequent investigation revealed that anti-Jk^b had been identified in 2003 at a different hospital. This laboratory has since changed its policy to issue red cell antibody cards to all patients with newly identified antibodies and to acquire a transfusion history for patients on long-term transfusion support.

COMMENTARY

Patients with sickle cell disease were again the subject of acute and delayed transfusion reactions. One patient died following an episode of post-transfusion hyperhaemolysis; another probably had a DHTR that was overlooked because all of the symptoms were attributed to sickle crisis and further transfusion of antigen-positive red cells could have been avoided; a third could have avoided a DHTR if a transfusion history had been known or if the patient had been carrying an antibody card. A distinction between a sickle crisis and immune haemolysis can be difficult but is aided by serial Hbs, reticulocyte counts, HbS/A% and urinary Hb high-performance liquid chromatography (HPLC).

There is not always any laboratory evidence of haemolysis in the cases reported as AHTRs, although red cell antibodies were detected in all cases. It is difficult to be sure about the relationship between the reaction and the antibody.

This is the first year that data relating to simple alloimmunisation have been collected. There was a clear overlap between the cases reported as DHTR and those reported as alloimmunisation. The definitions may have to be reviewed for future years.

In 3 cases (1 acute and 2 delayed) an antibody was only detectable in an eluate made from the patient's red cells. This is a recurring theme, but despite this an eluate was not tested in the majority of cases.

Recommendations

- Clinicians looking after patients with sickle cell disease should be aware that symptoms of a sickle cell crisis occurring up to 14 days post transfusion could be due to a DHTR, and should send samples for serological investigation.

  Action: HTCs

- Clinicians should be aware of the existence of hyperhaemolysis in sickle cell disease in which the Hb drops to levels lower than pre transfusion. Urine Hb HPLC can be useful to demonstrate the presence of both HbS and HbA and advice on the use of IVIg and/or steroids should be sought from a specialist unit or the Blood Service.

  Action: HTCs

For active recommendations and an update on their progress, please refer to the SHOT website.

13. Transfusion-Related Acute Lung Injury (TRALI)

Definition

Transfusion-related acute lung injury is defined as acute dyspnoea with hypoxia and bilateral pulmonary infiltrates during or within 6 hours of transfusion, not due to circulatory overload or other likely causes.

DATA SUMMARY

Total number of cases	**15**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**2**	Deaths due to transfusion	**0**
		FFP	**0**	Deaths *probably/likely* due to transfusion	**0**
		Platelets	**2**	Deaths *possibly* due to transfusion	**1**
		None identified	**11**	Major morbidity	**14**

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**7**	≥18 years	**14**	Emergency	**8**	A&E	**0**
Female	**8**	16 years to <18 years	**0**	Routine	**5**	Theatre	**0**
Not known	**0**	1 year to <16 years	**0**	Not known	**2**	ITU/NNU/HDU/recovery	**0**
		>28 days to <1 year	**0**				
		Birth to ≤28 days	**1**	In core hours	**0**	Wards	**0**
		Not known	**0**	Out of core hours	**0**	Community	**0**
		Total	**15**	Not known	**15**	Outpatient/day unit	**0**
						Not known	**15**

Fifteen case reports of suspected TRALI were analysed and the assessed probability of TRALI is shown in Table 42. Three patients died, 1 of whom had possible TRALI after massive transfusion of RBCs and FFP; the other 2 were assessed as unlikely to have had TRALI. One patient had required prolonged mechanical ventilation (>47 days) but this case was assessed as unlikely to have been TRALI. All other patients recovered fully from their respiratory events. All except 2 incidents occurred in 2010, with 2 incidents at the end of 2009.

Figure 12
Number of suspected TRALI cases and deaths at least possibly related to TRALI by year of report

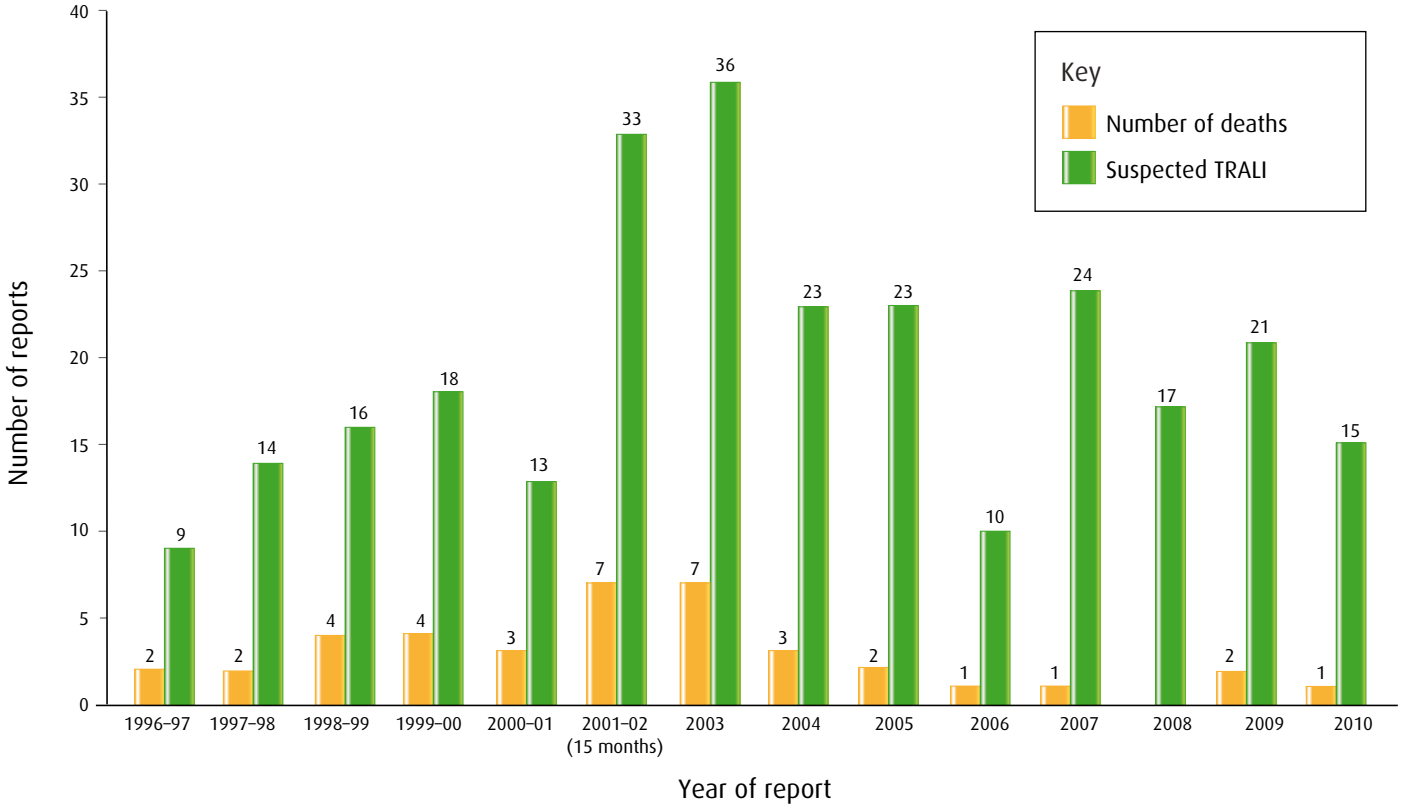
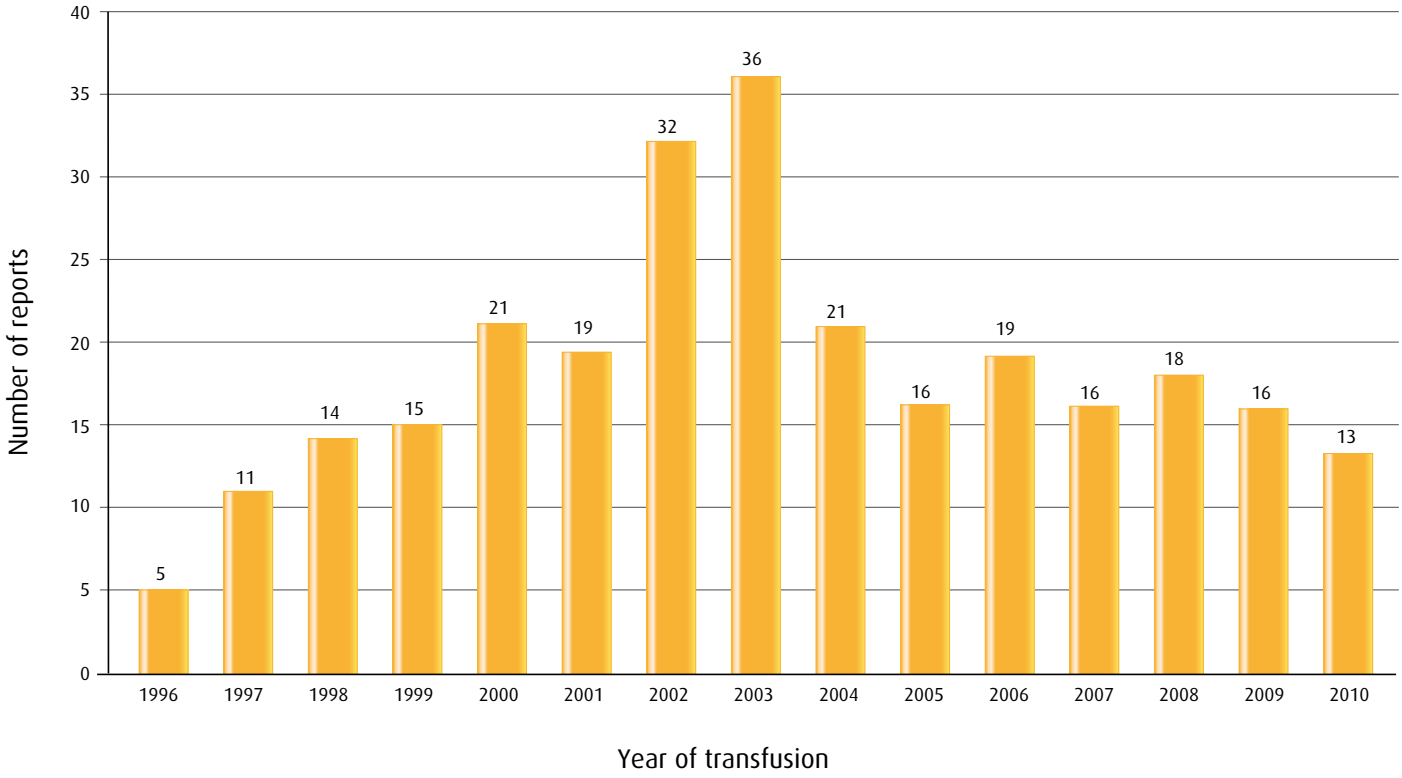


Figure 13
Number of TRALI cases by year of transfusion



Assessment of TRALI cases

There is no diagnostic test for TRALI and it is readily confused with other causes of acute lung injury (ALI), circulatory overload or infection. Many cases are complex, with several potential contributory factors. The probability of TRALI has been assessed in each case (see Table 42). Clinical factors which influence this assessment include timing, radiological features, possibility of infection, other risk factors for ALI/ARDS, evidence of circulatory overload and/or impairment of cardiac function, pre-existing cardiac, pulmonary, renal, hepatic or other disease, and response to diuretics. Serological results are also considered. Cases are still included in this report if it is thought that both TRALI and another risk factor such as cardiac failure contributed to the clinical events.

Two intensive care specialists and a transfusion medicine expert (TRALI expert panel) assessed all NHSBT cases (10 of 15 cases) before laboratory investigation. NIBTS also refer cases to the same intensive care specialists for assessment. A transfusion medicine specialist, who has reviewed SHOT TRALI reports for the past 7 years, has subsequently assessed all cases, taking account of the results of TRALI investigations.

As in previous years, cases were divided into four groups (as shown in Table 42):

Highly likely where there was a convincing clinical picture and positive serology

Probable where there was either a less convincing history and positive serology or a good history and less convincing or absent serology

Possible where either the clinical picture or serology was compatible with TRALI, but other causes could not be excluded

Unlikely where the picture and serology were not supportive of the diagnosis

Table 42
TRALI case probability (SHOT criteria)

TRALI case probability (SHOT criteria)	No. of cases
Highly likely	1
Probable	2
Possible	5
Unlikely	7
Total	**15**

Patients

Age

Patient ages ranged from 16 days to 71 years with a median age of 46 years. One patient was aged less than 18 years (pre-term baby); this case was classified as unlikely to be TRALI.

Clinical specialty

This year the most frequent specialty was surgery (6 cases), followed by medicine (3) and haematology/oncology (3), obstetrics and gynaecology (O&G) (2) and paediatrics (1).

Analysis of cumulative figures since 1996 from 272 reports of suspected TRALI has shown that haematology/oncology combined has provided the highest number of reports of suspected TRALI (92, 34%) and surgery the second highest (89, 33%). General medicine was reported as the specialty in 33 cases (12%). Denominator data are not available.

Clinical presentation

All cases, by definition, had been hypoxic with bilateral pulmonary infiltrates on CXR. Fourteen patients were treated in ITU, of these 6 were already on ITU before the event. Eleven patients required invasive mechanical ventilation for between 1 and >47 days (median 3). Other associated clinical features were under-reported this year.

Patient outcomes

Three patients died; 1 death was possibly related to TRALI (imputability 1) and the other 2 were considered unrelated to TRALI. One patient remained on a ventilator for >47days after the event (classified as unlikely to have been TRALI). Eleven patients made a full recovery.

The patient who died, possibly related to TRALI, had a massive transfusion of 13 RBC and 8 FFP for an upper GI bleed and died later that day of cardio-respiratory failure. The differential diagnosis was wide and a patient sample was unavailable for complete TRALI investigation. She had also suffered a cardiac arrest 10 days before this event. TRALI was not considered a likely reason for her respiratory failure based on the reported clinical information.

Laboratory investigations

All cases were referred by hospital staff to a Blood Service laboratory. Complete TRALI investigation results were available in 9 cases, results were incomplete in 3 cases and investigations were not undertaken after TRALI expert panel advice in 3 other cases. The panel advised that these events were more likely to be due to alternative causes.

Donor antibodies

Concordant donor HLA antibodies were found in donors of transfused components in 4 cases (2 HLA class I only, 1 HLA class II only and 1 with both HLA class I and class II). No case had proven concordant granulocyte antibodies. All donors found to have concordant leucocyte antibodies were female. Male donors of components transfused within 6 hours of the event, who had a history of past transfusion themselves, were routinely investigated but none was identified with concordant antibodies. Untransfused males were generally investigated if all other donors had been investigated and excluded, and no other likely cause for respiratory deterioration was present. All individuals who have been transfused since 1980 have been excluded from donation in the UK since 2004.

Patient antibodies

Patients are no longer routinely tested for leucocyte antibodies because all components except granulocytes are now leucodepleted in the UK. Such testing is confined to recipients of granulocytes (apheresis or buffy coat).

Components

All implicated components with proven concordant antibodies were donated by females. Details of concordant antibodies, components and details of other potential contributory factors are tabulated in Table 43.

Table 43
Cases with concordant antibodies – specificities and implicated components

Antibody	Concordant specificities	Component/s*	Other risk factors
HLA class I	HLA-B60, HLA-C10	RBCOA	Sepsis, TACO could not be excluded
HLA class I	HLA-HLA-A68, HLA-C10	RBCOA (22 mL only)	Sepsis, renal impairment – note only 0.25 mL plasma in transfused RBCOA
HLA class II	HLA-DR4	Apheresis platelets	Evidence of cardiac failure
HLA class I and class II	HLA-A25, HLA-DR51	Platelet pool – donor of both plasma and buffy coat*	On ventilator post coronary artery bypass graft

** Platelet pools are produced by pooling components from four donors. One donor (preferentially male) contributes a whole unit of plasma (nominally 300 mL) and a buffy coat (platelets suspended in approximately 30 mL of plasma), three other donors (either gender) each contribute a buffy coat. RBCOA, red blood cells in optimal additive solution.*

Classification of cases according to Canadian Consensus Criteria[1,2]

All 15 reports were also separately classified using the Canadian Consensus Criteria to allow international comparison (see Table 44).

Table 44
TRALI case probability (Canadian Consensus Criteria)

TRALI probability (consensus panel criteria)	No. of cases
TRALI	1
Possible TRALI	14
Total	**15**

Case 1 – TRALI highly likely

TRALI follows receipt of platelet pool suspended in female donor plasma

A middle-aged male developed oozing following coronary artery bypass grafting and was transfused with a platelet pool. He was already on invasive ventilation on ITU at this time. He became hypoxic (pO_2 9.7 kPA), hypercapnic and hypotensive within 50 minutes of transfusion. He was afebrile with a normal central venous pressure (CVP) level and his electrocardiogram (ECG) showed sinus tachycardia only. His echocardiogram (ECHO) showed poor right ventricular function and CXR showed bilateral infiltrates. He remained on mechanical ventilation for 3 days, following which he made a full recovery.

Investigation of all four female donors who contributed to this platelet pool identified that two of them had HLA antibodies. The female donor who had contributed both the plasma to suspend the pool and a buffy coat had antibodies concordant with recipient HLA class I and class II (HLA-A25 and HLA-DR51). Another female donor had non-concordant HLA antibodies. It was concluded that this case was highly likely to be TRALI.

Case 2 – TRALI probable

TRALI follows transfusion of apheresis platelets

An elderly female had cirrhosis with coagulopathy and ischaemic heart disease (IHD). She had undergone an elective TKR and was transfused with FFP (2 units) and platelets (2 units) to cover the removal of lines and epidural. She became suddenly breathless around 30 minutes after completing her transfusion and developed hypoxia, hypercapnia, fever and clinical signs of heart failure. Her CXR showed non-specific bilateral shadowing and she was known to have impaired left ventricular function on a previous ECHO. She was admitted to ITU and ventilated for 5 days, following which she made a full recovery. She was also treated with diuretics and IV fluids.

The female donor of 1 of the transfused platelet units (apheresis) was found to have multiple HLA antibodies, including concordant HLA class II antibodies (HLA-DR4). The other three donors were untransfused males. This case was assessed as probable TRALI, rather than highly likely, because there were also features consistent with cardiogenic pulmonary oedema.

Case 3 – TRALI possible

Respiratory deterioration after 22 mL RBCOA containing HLA antibodies, coincidental or causative?

A male in his 60s was admitted with breathlessness, chest infection and WCC 122 × 10^9/L. He was diagnosed with AML and treated with antibiotics and cytotoxic chemotherapy, including all-trans retinoic acid (ATRA). He was transfused uneventfully with platelets 3 days later, while already requiring oxygen support. On the next day, his antibiotics were changed and his oxygen saturation was 95% on 5 L/min oxygen. A further unit of platelets was transfused, followed by RBCOA. The unit of RBCOA was commenced at 20.05 hours but was discontinued at 20.20 after only 22 mL had been transfused because he developed bronchospasm, severe respiratory problems and tachycardia. His oxygen saturation dropped to 82% and he needed increased supplemental oxygen (15 L/min). He was treated with nebulisers and hydrocortisone but no CXR was performed. Two days later he became more unwell again with increased breathlessness and haemoptysis. At this stage a CXR showed 'complete white out' and he was neutropenic, septic and had renal impairment. He was then transfused with 2 units of platelets followed by part of a unit of RBCOA, which was associated with a slight temperature rise and respiratory distress. He responded to a combination of diuretics, antihistamine and hydrocortisone and was not admitted to ITU.

The TRALI expert advice, before the laboratory investigation, was that there was a 'full house' of risk factors for respiratory deterioration, including cytokine upregulation by leukaemia, cytotoxic chemotherapy and infection, chest infection and lots of volume going in to a very sick patient. It could easily be exacerbation of infection, TACO or TRALI. Bronchospasm is reported very rarely in likely cases of TRALI.

Donors of the units transfused in the 6 hours before the first event were investigated. The male platelet donor had no leucocyte antibodies. The female donor of the RBCOA had HLA class I antibodies that were concordant with both HLA-A68 and HLA-C10 in the patient. Only 22 mL of this unit was transfused containing a calculated volume of 250 µL of plasma. On balance, it was considered more likely that the concordant HLA antibodies were coincidental rather than causative and the case has been assessed as possible TRALI.

COMMENTARY

- Observed rates of TRALI remain consistently lower than in 2003–04, when TRALI risk reduction strategies were first initiated.
- Three deaths occurred, 1 was only possibly related to TRALI and 2 were unrelated.
- Female donors were implicated in all 4 cases where concordant donor HLA antibody was found.
- All UK Blood Services currently aim to use male donors to provide 100% FFP and plasma for platelet pooling.
- Disappointingly, 1 case of probable TRALI followed transfusion of a platelet pool suspended in female donor plasma that was subsequently found to have concordant HLA antibodies. This reinforces the absolute requirement to achieve 100% use of male plasma for suspension of platelet pools across the UK.
- One case of probable TRALI followed transfusion of an apheresis platelet donation from a female donor. New female donors are routinely screened for HLA/HNA antibodies before acceptance as platelet apheresis donors but existing female donors have not been tested by all Blood Services. Additional testing after subsequent pregnancies has not yet been introduced across all services.
- Suspected cases of TRALI were reported more promptly in 2010 than in previous years. Thirteen of 15 reports related to events that occurred in 2010 and 2 occurred late in 2009.

Recommendations

- Robust systems must be put in place to prevent issue of female FFP or platelet pools suspended in female donor plasma.

  Action: UK Blood Services

- A risk assessment should be conducted of screening existing female platelet apheresis donors for HLA and granulocyte antibodies, and for retesting for these antibodies after subsequent pregnancies.

  Action: UK Blood Services

- Transfusion-related respiratory events that occur later than the accepted 6-hour definition for TRALI should be reported to SHOT in another category (e.g. TAD).

  Action: HTTs

For active recommendations and an update on their progress, please refer to the SHOT website.

14. Transfusion-Associated Circulatory Overload (TACO)

Definition

Transfusion-associated circulatory overload includes any four of the following occurring within 6 hours of transfusion:

- acute respiratory distress
- tachycardia
- increased blood pressure
- acute or worsening pulmonary oedema
- evidence of positive fluid balance.

DATA SUMMARY

Total number of cases	**40**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**25**	Deaths due to transfusion	**1**
		FFP (untreated)	**3**	Deaths *probably/likely* due to transfusion	**3**
		Platelets	**1**	Deaths *possibly* due to transfusion	**2**
		Multiple components	**11**	Major morbidity	**15**

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**13**	≥18 years	**40**	Emergency	**16**	A&E	**2**
Female	**27**	16 years to <18 years	**0**	Routine	**20**	Theatre	**3**
Not known	**0**	1 year to <16 years	**0**	Not known	**4**	ITU/NNU/HDU/recovery	**6**
		>28 days to <1 year	**0**				
		Birth to ≤28 days	**0**	In core hours	**15**	Wards	**25**
		Not known	**0**	Out of core hours	**9**	Community	**1**
		Total	**40**	Not known	**16**	Outpatient/day unit	**2**
						Not known	**1**

A total of 33 questionnaires on TACO were received; 1 was transferred in from the ATR section, 2 from TAD and 4 from the TRALI section, resulting in a total of 40 cases, which are analysed in this chapter.

Definition

Cases were assessed by the reviewer for probability for a diagnosis of TACO based on the ISBT definition, available on the SHOT website (www.shotuk.org).[1] Cases that fulfilled these criteria but occurred between 6 and 24 hours were also included.

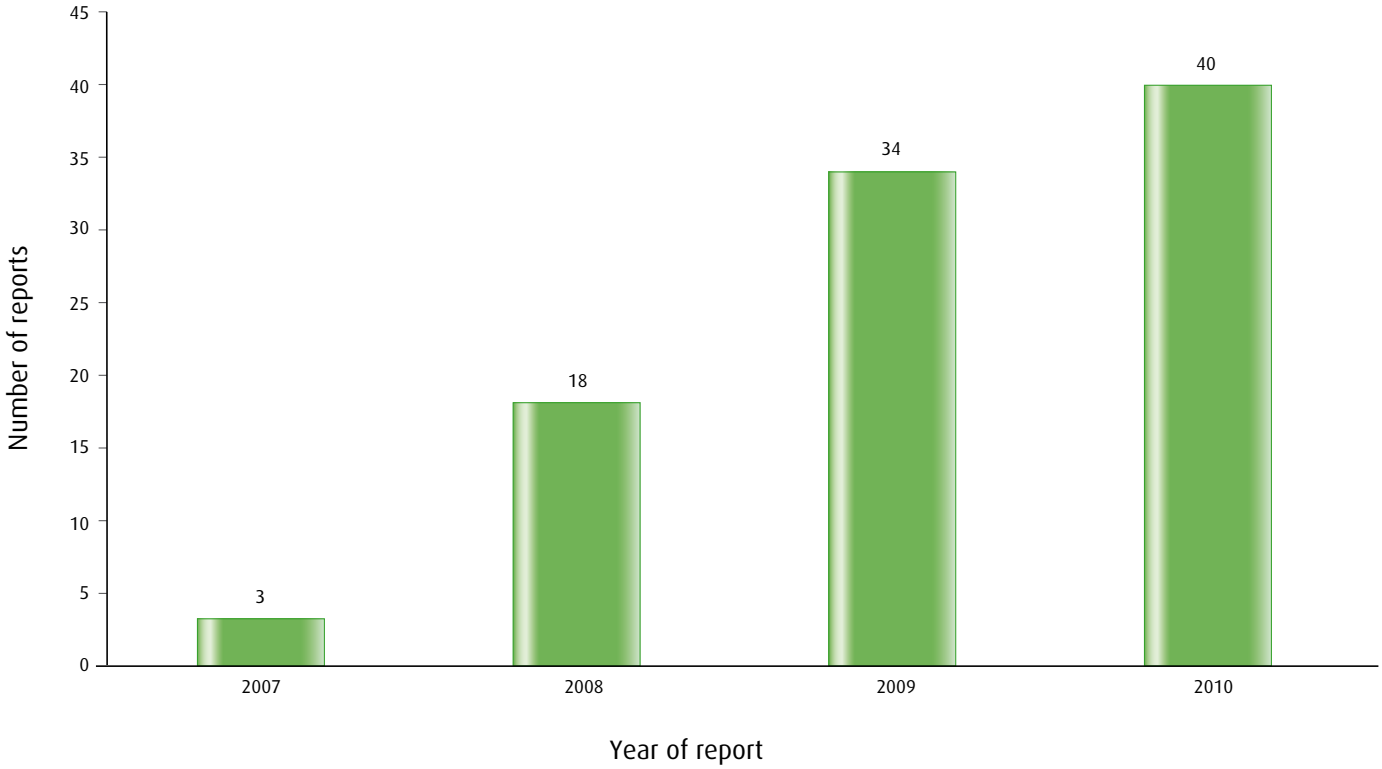
Patients

There were 13 men and 27 women. The age range was 27–91 years, with 23 patients (57.5%) 70 years or more and 7 patients <50 years. There were no patients under 18 years.

Table 45
TACO case probability based on ISBT criteria

TACO case probability (ISBT criteria)	No. of cases
Highly likely	13
Probable	20
Possible	7
Total	**40**

Figure 14
Number of cases of TACO reported to SHOT each year



**TACO was introduced as a SHOT reporting category in 2008.*

Mortality *n* = 6

There were 6 deaths where the transfusion was contributory: imputability ≥2 in 4 (Cases 1, 3, 4 and 5) and 2 where the possibility that TACO had contributed to death could not be excluded: imputability 1 (Cases 2 and 6). These are detailed below.

Case 1

TACO following RBC transfusion to elderly male with renal impairment and cardiac failure

An 83-year-old male with refractory anaemia related to CRF received 2 units of RBCs, each over approximately 1.5–2.5 hours. He had continuing bradycardia during the second unit. He remained stable, but the bradycardia persisted at 40–45 beats per minute (bpm). Within 15 minutes of the start of the third unit of RBC, he became unresponsive with no assessable cardiac output. An arrest call was put out and resuscitation commenced, which was ultimately unsuccessful. A post-mortem examination showed acute left ventricular failure (LVF), hypertensive heart disease with mitral valve prolapse and hypertensive nephropathy.

Case 2

TACO in elderly patient with hypoalbuminaemia and fluid overload

A 73–year-old female with a chronic anaemia associated with gastric malignancy and pulmonary embolism (PE) was admitted to hospital. She had hypoalbuminaemia and fluid overload. She was given a 2 unit RBC transfusion and became SOB 85 minutes into the second unit of RBC. She also developed tachycardia, pulse 140 bpm with BP 177/82, nausea and back/chest pain. The O_2 saturation was 66% on 3 L of oxygen and she had pulmonary oedema. She was given IV furosemide and hydrocortisone, and transferred to the HDU. TACO was considered to be highly likely. The following day she developed a haemothorax. Two days post transfusion she was documented to have further minor PEs, a lower respiratory tract infection and pulmonary oedema. She was transfused 4 further RBC units with careful fluid management and diuretic cover, apparently uncomplicated, on the cardiac care unit. Four days after the development of TACO her condition deteriorated through the night and she died.

Case 3

TACO after RBC transfusion to elderly female with pre-existing cardiac failure

An 86-year-old female with chronic anaemia associated with chronic myeloid leukaemia (CML) received a 2-unit RBC transfusion in the haematology day unit over approximately 5 hours. She had pre-existing cardiac failure with pitting oedema up to the level of her buttocks. On getting up to go home she became breathless, tachycardic (pulse 140 bpm) and hypertensive (BP 192/80), with a reduced O_2 saturation of 78%. The jugular venous pressure (JVP) was raised at +5 cm, and she had bilateral basal crepitations. The CXR appearances were consistent with pulmonary oedema. Treatment included oxygen support with continuous positive airway pressure (CPAP), but she subsequently died.

Case 4

TACO after oral diuretics withheld in elderly patient with cardiac failure because 'nil by mouth'

An 84-year-old male with congestive cardiac failure (CCF) associated with IHD, on oral furosemide, isosorbide mononitrate and enalapril, was admitted with melaena. The Hb was 7.9 g/dL. He was transfused 3 units of RBC, each over 3 hours. However, because he was nil by mouth for endoscopy, his oral medication was withheld. No parenteral diuretic was substituted. He developed pulmonary oedema with pO_2 6.3 kPa, and received CPAP and diuretic therapy, but he died.

Case 5

TACO following RBC transfusion to elderly female with renal impairment and cardiac failure

A frail 91-year-old female with a history of CRF and CCF had anaemia, Hb 8.1/dL, associated with intermittent rectal bleeding. She was stable with pulse 70 bpm, BP 110/50 and good oxygen saturation. She became SOB, pO_2 8 kPa, during transfusion of a unit of RBC given over 5 hours and covered with furosemide 80 mg IV. The next morning a second RBC unit was transfused, making her progressively unwell with 15 L of oxygen required to maintain normal saturation. She arrested and later died.

Case 6

TACO following RBC transfusion to elderly female with chronic anaemia secondary to myeloma

An 85-year-old female with stage 3 myeloma and chronic anaemia, Hb 6.5 g/dL, became SOB during transfusion of the second unit of a 2-unit RBC transfusion. Each unit was given over 4 hours. The transfusion was stopped. She became tachycardic (pulse 110 bpm), hypertensive (BP 203/110) and hypoxic, with mild to moderate LVF. She was transferred to the coronary care unit, but her renal function deteriorated and she died 11 days later.

Learning point

- TACO is potentially avoidable in many cases. Doctors should undertake pre-transfusion clinical assessment, taking into account concomitant medical conditions that increase the risk of TACO (cardiac failure, renal impairment, hypoalbuminaemia, fluid overload) and consider diuretic cover (e.g. furosemide).

Major morbidity *n* = 15

There were 15 cases of major morbidity. Thirteen of these 15 patients required ITU or HDU admission and/or ventilation. The remaining 2, who were already on ITU, required increased ventilatory support after the development of TACO.

Of the remainder (*n* = 19), 12 were administered O_2, 2 had CPAP and 13 were stated to have received diuretic therapy.

Clinical details and transfused fluids in TACO cases

Details of the rate of transfusion were reported in 30/40 cases (75%). In 10 of 16 cases where RBC were transfused in the absence of suspected haemorrhage, the mean duration of transfusion/RBC unit was approximately 2 hours 30 minutes; in 3 cases it was 4 hours and in 3 cases it was not stated or not recorded. Details on fluid balance were supplied by the reporter in 11/40 (27.5%) and not recorded, not stated or incomplete in the remainder.

The median time between the transfusion and the onset of symptoms was 0–2 hours in 19/40 cases (47.5%), 2–6 hours in 16 cases (40%), and between 6 and 24 hours in the remainder (13.1% (5/40); 6–12 hours in 3 and 12–24 hours in 2 cases).

Twenty-three of the 40 patients (57.5%) had 1 or more concomitant medical conditions that increase the risk of TACO: cardiac failure, renal impairment, hypoalbuminaemia, fluid overload (not stated in 1 case).

Learning points

- Nurses should monitor the rate of transfusion and fluid balance as these factors influence the risk of a patient developing TACO.
- SHOT reports indicate that TACO can occur up to 24 hours after the transfusion, therefore the patient should be monitored accordingly, as advised in the BCSH guidelines on the administration of blood components.[2]

Acute haemorrhage cases in which more than 1 component was transfused *n* = 7

There were 7 cases of TACO in which RBC plus other blood components were administered for major acute haemorrhage: post-partum (3), postoperative (2) and GI haemorrhage (2).

Case 7

TACO following transfusion for massive obstetric haemorrhage

This female had a PPH post Caesarean section. She received 7 units of RBC, 2 units of FFP and 1 pool of platelets transfused rapidly, following which she starting coughing up frothy white sputum. The O_2 saturation dropped to 85%, and she became hypotensive, tachycardic (140 bpm), temperature 39°C (pre-transfusion temperature unavailable), acidotic pH 7 and pO_2 11 kPa on 100% oxygen. A CXR indicated pulmonary oedema. Furosemide and noradrenaline were given with a good response. An ECHO later showed good ventricular function.

Cases in which RBC transfusion was implicated *n* = 34

RBC were transfused in 34 cases. In 16 of these RBC were transfused for acute haemorrhage, in 7 cases together with (an)other component(s) (detailed above). In a further 18 cases RBC were administered in the absence of suspected acute haemorrhage. In these 18 cases, TACO occurred after >3 units in 1, after ≤2 units in 15 and after ≤1 unit in 2. In 12 of these 18 cases (66.7%) patients were ≥70 years (mean 81.8 years). Five of the remainder (not stated in 1) who were <70 years (range 42–68 years) had risk factors that increase the risk of TACO: fluid overload (3), hypoalbuminaemia (1) and fluid overload, hypoalbuminaemia and renal impairment (1). In 4 of these 18 cases the mean transfusion duration/RBC unit was 4 hours and in a further 10 it was approximately 2 hours 15 minutes (range 1 hour 30 minutes–3 hours 45 minutes). In 4 cases the duration of transfusion was not stated or recorded.

Learning points

- TACO can occur after transfusion of small volumes of RBC, even ≤1 unit.
- Patients >70 years are particularly at risk of TACO following RBC transfusion in the absence of suspected acute haemorrhage.
- Patients <70 years are also at risk of TACO, particularly in the presence of factors that increase the risk of TACO: cardiac failure, renal impairment, hypoalbuminaemia and fluid overload.

Cases in which FFP was transfused *n* = 13

There were 13 cases in which FFP was implicated in TACO, of which 8 occurred in the context of acute haemorrhage. Of the remaining cases (5/13), in 2 cases FFP was transfused pre-procedure because of abnormal coagulation tests, in 2 cases FFP was transfused to patients with hepatic disease and in 1 case 1200 mL FFP was transfused without plasma exchange (PEX) to a 77-year-old male diagnosed to have thrombotic thrombocytopenic purpura (TTP). A volume of >1000 mL was transfused in 7 cases (volume unstated in 2).

Learning points

- There are few proven indications for FFP, but if FFP is indicated, the BCSH guidelines state that the conventional dose is 10–15 mL/kg, with the dose dependent on the clinical situation and its monitoring.[3]
- Plasma exchange (PEX) with FFP replacement (rather than FFP transfusion without PEX) is the mainstay of the treatment of TTP and has led to a reduction in mortality from >90% to approximately 20%. Patients diagnosed as having TTP should be transferred to a unit that can provide PEX as soon as is feasible, with FFP transfusion while this is being organised. SD FFP should be used (see Commentary).

Cases in which platelets were transfused *n* = 8

There were 8 cases in which platelets were transfused, of which 4 occurred in the context of acute haemorrhage. In 7 cases other components were also transfused, and in 1 case platelets only were transfused.

Procedural review

In 16/40 (40%) the case had been reviewed by the HTC and in 3/40 the case had been reported to the Trust clinical risk committee, with review stated to be pending in the remainder.

COMMENTARY

This year TACO has been implicated in 6 deaths (4 imputability ≥2; 2 imputability 1) and 15 cases of major morbidity, with these serious outcomes together comprising 52.5% (21/40) of cases analysed. While TACO may occur in approximately 6–8% of critically ill patients on ITU,[4] only 2 reported cases occurred in the ITU setting.

The number of cases of TACO reported has reached a plateau. Eleven of the 40 patients had haematological conditions, suggesting awareness of TACO among haematologists, but TACO probably remains under-reported.

Patients >70 years are particularly at risk of TACO following RBC transfusion in the absence of suspected acute haemorrhage. Patients <70 years are also at risk of TACO, particularly in the presence of factors that increase the risk of TACO: cardiac failure, renal impairment, hypoalbuminaemia and fluid overload. These factors occurred in 57.5% (23/40) of cases overall. The BCSH guidelines on the administration of blood components[2] do not address clinical assessment prior to transfusion, including for the risk of TACO, and measures to decrease the risk of TACO.

One fatal case (Case 4) was associated with failure to continue diuretic therapy in a patient who had known cardiac failure. While Li *et al*. suggest that pre-transfusion diuretic therapy was not found to be protective among medical ITU patients, it was acknowledged that infrequent use of diuretics in 9/51 (17.6%) TACO cases and 12/51 (23.5%) matched controls before transfusion in the study population made it difficult to draw a definite conclusion.[4]

It is of concern that details on fluid balance in the 24 hours prior to the reaction were supplied by the reporter in only 11/40 (27.5%) cases.

In 10 of 18 cases where RBC were transfused in the absence of suspected acute haemorrhage, the mean transfusion duration/RBC unit was approximately 2 hours 15 minutes, and 4 hours in the remaining 4 cases where information was supplied. The transfusion rate influences the risk of TACO, particularly in the elderly and in the presence of concomitant medical conditions that are risk factors for TACO. The *Handbook of Transfusion Medicine* (4th edition) recommends that all blood component transfusions are completed within 4 hours of removal from a controlled temperature environment.[5] This limit is designed to reduce the risk of bacterial growth and TTI, and is based on data relating to the 'lag phase' before bacteria begin to proliferate after removal from refrigeration. The BCSH guidelines note that the evidence for a strict 4-hour rule 'falls short of that required for a "must" recommendation', and recommend that this rule should continue to be applied in clinical practice wherever possible.[2]

TACO was associated with the transfusion of relatively modest volumes of RBC and other blood components. It has been suggested that the aetiology of TACO may be more complex than excessive blood volume. In a retrospective analysis in a single centre in the US, Blumberg *et al*. (2010) reported a substantial reduction in the incidence of TACO (to zero) and also of TRALI but not of allergic reactions following the implementation of universal leucodepletion.[6] In the UK, universal leucodepletion of all cellular components (except granulocytes/buffy coats) was implemented in late 1999.

The majority of cases of TACO occurred within 6 hours of the transfusion, but 13% occurred after 6 hours (6–12 hours in 3 cases and 12–24 hours in 2 cases), suggesting that the 6-hour cut-off for diagnosis of TACO merits consideration. Following last year's main recommendation on pulmonary complications of transfusion, SHOT is participating in a collaborative approach to further define these.

Cases of TACO following major obstetric haemorrhage continue to be reported, with a further 4 cases this year and a total of 7 cases since 2008. Contributory factors are difficulties in estimating actual blood loss, particularly because of the changing blood volume, and circulatory capacity. As a result patients may be over-transfused. There may also be a failure to recognise TACO in these young individuals, who are often regarded to be 'immune' to TACO.

FFP transfusion, particularly volumes >1000 mL of FFP, is a risk factor for TACO. There are few proven indications for FFP, but if FFP is indicated, a limiting factor to administration of an adequate volume of FFP may be the patient's ability to tolerate the volume transfused. The BCSH guidelines state that the conventional dose is 10–15 mL/kg, with the dose dependent on the clinical situation and its monitoring.[3] Prothrombin complex concentrates (PCC), in which the volume of a therapeutic dose is small, is the product of choice for urgent reversal of coumarin (warfarin) anticoagulation when

this is indicated. PCC may also be useful in the correction of coagulopathy in non-warfarinised patients with severe bleeding, where substantive data would be welcome.

In 1 case TACO was associated with (untreated) FFP transfusion without PEX. The mainstay of the treatment of TTP is PEX with FFP replacement, which has reduced mortality rates from >90% to approximately 20%. The DH recommends that because of the high donor exposure, adult patients with TTP should be treated with SD-FFP.[7] SD-FFP, unlike standard FFP, lacks high molecular weight vWF multimers and may be more effective than standard FFP in TTP, and has been shown to be associated with fewer allergic/urticarial and citrate reactions than the use of cryosupernatant in patients with TTP.[8]

Recommendations

- National guidelines are required on clinical assessment pre transfusion, which should include taking into account concomitant medical conditions that increase the risk of TACO (cardiac failure, renal impairment, hypoalbuminaemia, fluid overload) and measures to reduce the risk of TACO.

  Action: BCSH

- The rate of transfusion also merits review, particularly in patients >70 years and those with concomitant factors that increase the risk of TACO.

  Action: BCSH

For active recommendations and an update on their progress, please refer to the SHOT website.

15. Transfusion-Associated Dyspnoea (TAD)

Definition

Transfusion-associated dyspnoea is characterised by respiratory distress within 24 hours of transfusion that does not meet the criteria of TRALI, TACO or allergic reaction. Respiratory distress should not be explained by the patient's underlying condition or any other known cause. This will allow haemovigilance systems to classify all reported pulmonary reactions without the need for exceptions or inappropriate assignment.

DATA SUMMARY

Total number of cases	**35**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**23**	Deaths due to transfusion	**0**
		Platelets	**11**	Deaths *probably/likely* due to transfusion	**0**
		FFP	**4**	Deaths *possibly* due to transfusion	**0**
		Cryoprecipitate	**1**	Major morbidity	**6**
		≥2 components	**4**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**16**	≥18 years	**27**	Emergency	**6**	A&E	**0**
Female	**19**	16 years to <18 years	**1**	Routine	**27**	Theatre	**0**
		1 year to <16 years	**1**	Not known	**2**	ITU/NNU/HDU/recovery	**3**
		>28 days to <1 year	**3**				
		Birth to ≤28 days	**0**	In core hours	**24**	Wards	**26**
		Not known	**3**	Out of core hours	**9**	Community	**0**
		Total	**35**	Not known	**2**	Outpatient/day unit	**5**
						Not known	**1**

Nine reports of TAD were received; 28 more cases were transferred in: 26 from the ATR section where respiratory distress predominated, and 1 each from the TACO and TRALI sections. Two cases were transferred to the TACO section, resulting in a total of 35 cases, which are reported in this chapter.

Definition

Cases were assessed by the reviewer for probability of a diagnosis of TAD based on the ISBT definition.[1] A standardised definition under review will help haemovigilance organisations generate data that will be comparable at an international level.

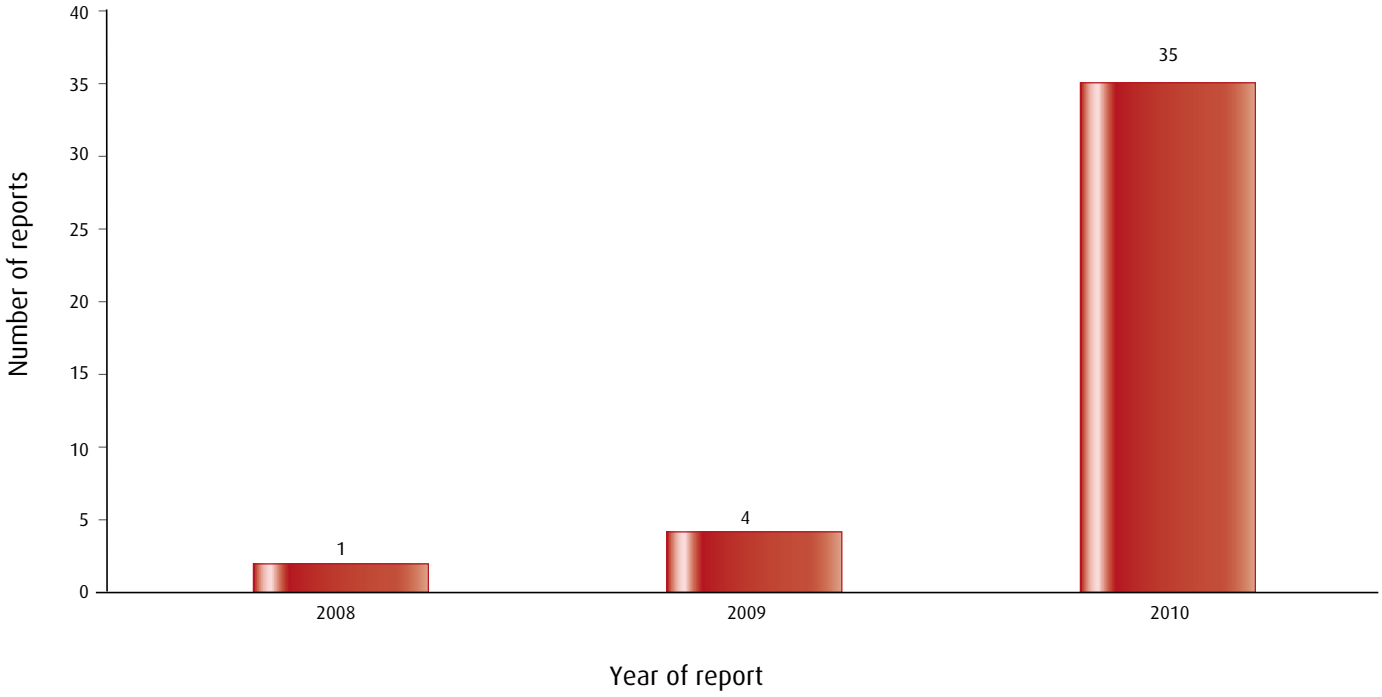
Patients

There were 16 males and 19 females. The age range was 3 months to 90 years. Six patients were under 18 years, of whom 3 were under 1 year. The mean age of patients >18 years was 63.8 years.

Table 46
TAD case probability based on ISBT criteria

TAD case probability (ISBT criteria)	No. of cases
Highly likely	5
Probable	7
Possible	20
Unlikely	3
Total	**35**

Figure 15
Number of cases of TAD reported to SHOT each year*



TAD was introduced as a SHOT reporting category in 2009.

Mortality *n* = 0

There were no reported deaths related to TAD.

Major morbidity *n* = 6

There were 6 cases of major morbidity, defined as the requirement for ITU admission and/or ventilation associated with TAD, which are described below (1 probable (Case 3) and the remainder possible cases of TAD). These cases are heterogeneous, but their unifying salient feature is respiratory distress. They contain elements of TACO, TRALI or ATRs, and even of bacterial sepsis, but they do not meet the criteria for any of these, nor can they be explained by the patient's underlying condition or any other known cause.

Case 1

TAD following RBC and platelet transfusion in a patient with AML and an upper respiratory tract infection

A 71-year-old male with AML admitted for chemotherapy was transfused 2 units of red cells and 1 pool of platelets between 11.00 and 14.30 hours followed by a pool of platelets between 14.30 and 15.00 hours. He had an upper respiratory tract infection for which he was treated with Tazocin® and gentamicin, which was switched to meropenem. At 15.30 hours he complained of retrosternal pleuritic pain. At 17.15 hours he developed severe dyspnoea with the O_2 saturation 83% on 10 L of O_2. There was no wheeze. He was tachycardic (pulse 130 bpm) and hypertensive (BP 230/120). He was treated with hydrocortisone, chlorpheniramine, salbutamol 5 mg and furosemide 40 mg IV with no effect. A CXR showed a 'white out'. He had type 1 respiratory failure and was admitted to the ITU for bilevel positive airway pressure (BIPAP).

Case 2

TAD in the context of sepsis and with some features suggestive of ATR, TRALI and TACO following a prophylactic platelet transfusion

A 60-year-old female with myeloma post-autologous SCT was given a pack of apheresis platelets following which she developed rigors, pyrexia, hypertension, tachycardia, nausea, respiratory distress, dyspnoea and headache. A further platelet transfusion was given 48 hours later with 'cover'. However, she developed severe tachycardia and respiratory failure with O_2 saturation 65% on 15 L of O_2 and required ITU admission and ventilation. A CXR was initially reported as consistent with TRALI, and later assessed to be pulmonary oedema due to severe left ventricular dysfunction. Both transfusions were given via a Hickman line, which was later found to be infected and removed. Further platelet transfusions given via a central line were uneventful.

Case 3

TAD with some features suggestive of ATR following a platelet transfusion for epistaxis

A 50-year-old male with myeloma, platelets 28 × 10^9/L associated with prolonged epistaxis, was transfused a pack of apheresis platelets. The transfusion passed without incident, but approximately 1 hour post transfusion he developed rigors and severe dyspnoea. Oxygen saturation levels dropped to 85–89%. He also developed pyrexia, with the temperature peaking at 39.5°C about 2 hours post transfusion. He was transferred to the ITU and received steroid, diuretics, antibiotics and oxygen.

Case 4

TAD following 9 mL of RBC

Following cardiac surgery, a 4-month-old girl's condition deteriorated during the night with respiratory distress, agitation and hypertension. Her Hb was 8.9 g/dL. The medical team decided to give a unit of RBC while considering the need to transfer her to the paediatric intensive care unit (PICU). After 9 mL of the RBC transfusion, within 15 minutes of starting, she developed pyrexia, the respiratory distress worsened, and there was an increase in pulse rate. The transfusion was stopped and piriton was given. She was transferred to the PICU and intubated.

Case 5

TAD associated with anaphylaxis following SD-FFP

A 21-year-old female with ALL post-bone marrow allograft underwent PEX, with SD-FFP (Octaplas®) to reduce transplant-mediated antibodies. During the procedure she experienced an anaphylactic reaction with dyspnoea. The cardiac arrest team was called and she required ITU admission. This case was categorised as TAD rather than ATR because dyspnoea was a predominant feature.

Case 6

TAD with some features of TACO and associated with sepsis after bowel resection following FFP and RBC transfusion

A 64-year-old male undergoing bowel resection received FFP (untreated) for a single coagulation factor deficiency and a RBC transfusion perioperatively. He was septic. Twelve to 24 hours later he developed rapidly progressive hypoxia, O_2 saturation 84–88%, with bilateral lung shadowing. The pulse was 95 bpm and BP 100/70. He was 1838 mL in positive fluid balance (4738 in and 2900 out) in the 48 hours prior to the reaction. He was treated with O_2 and IV fluids, and required ITU admission and ventilation.

Implicated components

Of the 35 patients 23 received RBCs, 11 received platelets (of which 7 were apheresis and 3 pooled), 4 received FFP (3 untreated and 1 SD-FFP) and 1 cryoprecipitate. Four of these 35 patients received ≥2 components (2 RBCs and platelets, 1 RBC and FFP (untreated) and 1 FFP (untreated) and cryoprecipitate).

Table 47

Ratios of reactions related to RBC alone vs. platelets alone, and RBC alone vs. FFP/cryoprecipitate compared with ratios of RBC vs. platelets and RBC vs. FFP/cryoprecipitate issued in 2010

	RBC:platelets	RBC:FFP
Cases of TAD	2.22:1	6.67:1
Components/products issued	8.83:1	4.63:1

These ratios suggest a possible preponderance of TAD associated with platelet transfusion, although a) this may reflect reporting bias as a number of patients (*n* = 12) were under the care of a haematologist and there was probably haematological input into several other cases, and b) the small total number of cases precludes any definitive conclusions.

Clinical features

The defining clinical feature was respiratory distress. In addition, 12 patients were stated to have tachycardia, 9 to have hypertension, 9 to have pyrexia with a temperature rise of >1.5°C and a further 3 to have rigors.

Oxygen saturation was measured in 26/35 (74.3%) cases and not measured in 4, with no information supplied by the reporter in the remaining 5. A CXR was performed in 11/35 (31.4%) cases and in the remainder (24/35, 68.6%) it was either not done (16/35, 45.7%) or no information was supplied (8/35, 22.9%). The majority of the cases where these investigations were not performed were in those transferred from the ATR section.

TAD occurred within 2 hours of the transfusion in 27/35 (77.1%) cases (unspecified in the remaining 7), and in <15 minutes in 18 (66.6%) of these 27. The reaction was stated to have occurred during the transfusion in a further 1 case. Five cases (14.3%) occurred after 2 hours (2–6 hours in 3 cases, 6–12 hours in 1 case and 12–24 hours in 1 case). Twelve of the 35 (34.3%) patients were under the care of a haematologist.

Procedural review

Procedural review had been undertaken in a total of 24/35 (68.6%) cases. Twenty-two cases had been reviewed by the HTT, in 1 case also by the HTC, in 1 also by another Trust risk review group; and in 1 by the HTC and another Trust risk review group. Two cases had been reviewed by the HTC and 10 cases were awaiting review.

Learning point

- Although the majority of cases occurred within 2 hours of the onset of transfusion, TAD can occur up to 24 hours after transfusion. Appropriate monitoring should therefore be undertaken, as detailed in the BCSH guidelines on the administration of blood components.[2]

COMMENTARY

This year there were 6/35 (17.1%) cases of major morbidity associated with TAD, which appears to be a clinically significant and heterogeneous entity and may include cases with more than one physiological mechanism.

TAD cases are heterogeneous, but their unifying salient feature is respiratory distress. They contain elements of TACO, TRALI or ATRs, and even of bacterial sepsis, but they do not meet the criteria for any of these, nor can they be explained by the patient's underlying condition or any other known cause.

More information about this group of complications is required to enable a systematic approach to the investigation and management of pulmonary complications of transfusion. No information was supplied on oxygen saturation in approximately 25% of cases, and in almost 70% of cases a CXR was either not done or no information was supplied. Appropriate investigation of cases of respiratory distress associated with transfusion includes assessment of oxygen saturation/arterial blood gases and a CXR. Provision of information by reporters is invaluable for the accurate classification of cases of pulmonary complications of transfusion.

TAD occurred within 2 hours of transfusion in the majority (>75%) of cases, and within 15 minutes of the start of the transfusion in over two-thirds of these. However, cases can occur up to 24 hours after transfusion, highlighting the need for appropriate monitoring during and after administration of blood components.[2]

The numbers of cases of TAD has increased, implying growing recognition. Approximately one-third of patients were under a haematologist and several other cases may have had haematological input, suggesting that much of the increased reporting is due to increased awareness among haematologists.

Recommendations

- Assessment of all cases of respiratory distress associated with transfusion should include assessment of oxygen saturation/arterial blood gases and CXR appearances.

  Action: HTTs

- In cases of suspected ATR where the predominant feature is respiratory distress, the case should be reported to SHOT as a pulmonary complication of transfusion (e.g. TAD).

  Action: HTTs

For active recommendations and an update on their progress, please refer to the SHOT website.

16. Post-Transfusion Purpura (PTP)

Definition

Post-transfusion purpura is defined as thrombocytopenia arising 5–12 days following transfusion of red cells associated with the presence in the patient of antibodies directed against the HPA systems.

DATA SUMMARY

Total number of cases	1	*Implicated components*		*Mortality/morbidity*	
		Red cells	1	Deaths due to transfusion	0
		FFP	0	Deaths *probably/likely* due to transfusion	0
		Platelets	0	Deaths *possibly* due to transfusion	0
		Other (granulocyte)	0	Major morbidity	0
		Unknown	0		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	0	≥18 years	1	Emergency	0	A&E	0
Female	1	16 years to <18 years	0	Routine	1	Theatre	0
Not known	0	1 year to <16 years	0	Not known	0	ITU/NNU/HDU/recovery	0
		>28 days to <1 year	0				
		Birth to ≤28 days	0	In core hours	1	Wards	1
		Not known	0	Out of core hours	0	Community	0
		Total	1	Not known	0	Outpatient/day unit	0
						Not known	0

Only 1 questionnaire was received that fulfilled the definition of PTP this year.

Case 1

Purpura 5 days after transfusion

A 45-year-old female patient was transfused, uneventfully, with 3 units of red cells for treatment of post-chemotherapy anaemia. Five days later she presented with purpura and her platelet count was found to have dropped to 10 × 10^9/L from a pre-transfusion level of 238 × 10^9/L. She had not received any previous transfusion but had had 3 children more than 20 years ago. Investigations identified an HPA-5b alloantibody. She recovered uneventfully without specific treatment. Her platelet count recovered to over 50 × 10^9/L within 14 days and to over 100 × 10^9/L within 21 days.

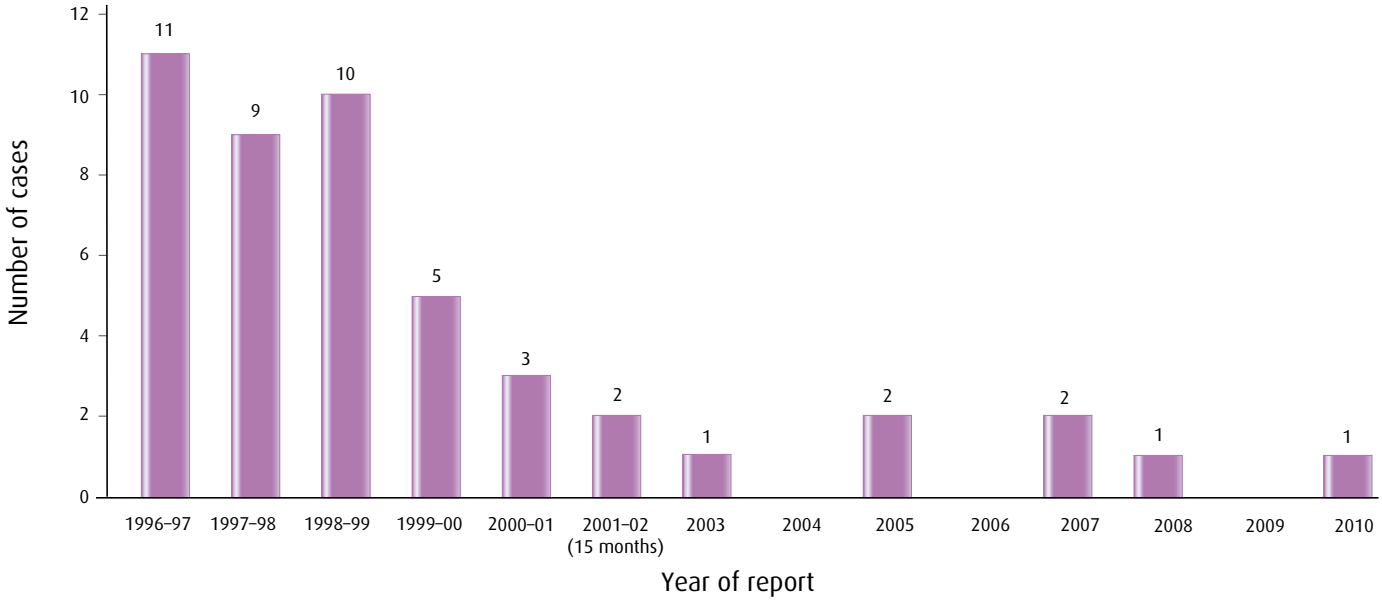
Cumulative data 1996–2010

Figure 16 shows the annual numbers of cases of PTP reported to SHOT with confirmed HPA alloantibodies since 1996; a total of 47 reports. A sustained decrease in the number of these cases has been seen since the introduction of universal leucodepletion in late 1999. This is likely to be related to the removal of most platelets, as well as leucocytes, by leucodepletion filters.

Since 1996, HPA-1a antibodies have been identified most frequently. Thirty-six patients (76%) had HPA-1a antibodies either alone (31 cases) or in combination with other antibodies (5 cases). In 11 cases PTP was due to other HPA antibodies without HPA-1a. Other HPA antibodies included those specific for: HPA-1b, -2b, -3a, 3b, -5a, -5b and 15a. Of these, HPA-1b and HPA-3a antibodies were found most frequently (5 cases each). HPA-5b antibodies were found in only 2 cases of PTP. All except 2 cases caused by non HPA-1a antibodies occurred before the introduction of universal

leucodepletion. Since then, 10 cases have been caused by HPA-1a antibodies alone, 1 case has been caused by HPA-1b and 1 by HPA-5b antibodies. Antibodies against HPA-1a are the most common cause of both PTP and neonatal alloimmune thrombocytopenia.

Figure 16
Number of cases of confirmed PTP reported to SHOT each year



Further information about PTP is available in *Practical Transfusion Medicine*.[1]

Recommendation

- Clinicians are encouraged to contact Blood Services if they suspect PTP.

Action: HTCs

For active recommendations and an update on their progress, please refer to the SHOT website.

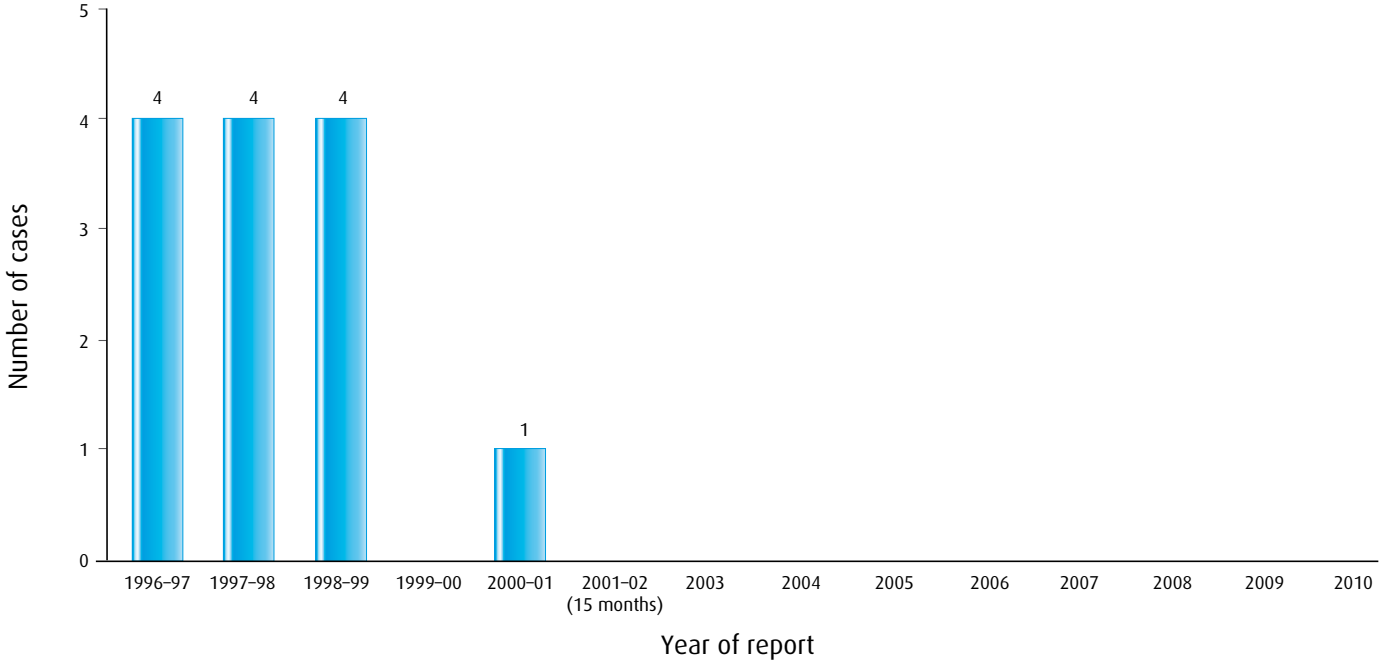
17. Transfusion-Associated Graft-Versus-Host Disease (TA-GvHD)

Definition

Transfusion-associated graft-versus-host disease is a generally fatal immunological complication of transfusion practice, involving the engraftment and clonal expansion of viable donor lymphocytes contained in blood components in a susceptible host. It is characterised by fever, rash, liver dysfunction, diarrhoea, pancytopenia and bone marrow hypoplasia occurring less than 30 days following transfusion. The diagnosis is usually supported by skin/bone marrow biopsy appearance and/or the identification of donor-derived cells, chromosomes or deoxyribonucleic acid (DNA) in the patient's blood and/or affected tissues.

No new case of TA-GvHD was reported in 2010.

Figure 17
Number of cases of TA-GvHD reported to SHOT each year



COMMENTARY

No report of TA-GvHD has been received during the last 8 years, despite a failure to provide irradiated components to 686 patients at risk of this adverse reaction. A total of 13 cases of TA-GvHD has been reported to SHOT since 1996, all of which were fatal. Only 1 case has occurred since the introduction of leucodepletion of all components except granulocytes/buffy coats in late 1999. Two cases have occurred following transfusion of leucodepleted components (1998–99 and 2000–01).

Although the risk of TA-GvHD is small it remains essential to irradiate blood components for all patients who are at risk of this lethal complication. This year 68 patients who had a requirement to receive irradiated blood in accordance with BCSH guidelines[1] received non-irradiated components but fortunately did not develop TA-GvHD. Fifty-nine of these were attributed to clinical errors and 9 to laboratory errors. In the last 8 years there has been a total of 664 of such cases, none of whom developed TA-GvHD.

Recommendations

- There are no new recommendations.

For active recommendations and an update on their progress, please refer to the SHOT website.

18. Transfusion-Transmitted Infection (TTI)

Definition

A report was classified as a transfusion-transmitted infection if, following investigation:

- the recipient had evidence of infection following transfusion with blood components and there was no evidence of infection prior to transfusion and no evidence of an alternative source of infection;

and, *either:*

- at least one component received by the infected recipient was donated by a donor who had evidence of the same transmissible infection

or:

- at least one component received by the infected recipient was shown to contain the agent of infection.

DATA SUMMARY		
Total number of cases	**0**	**There were no *proven* cases of TTIs reported in 2010**

Most reports of suspected viral and bacterial TTIs are received and investigated by the UK Blood Services and then reported to the NHSBT/HPA Epidemiology Unit. From here, data are included in the SHOT report. A number of reports were also received from SHOT via the MHRA's online reporting system for Serious Adverse Blood Reactions and Events (SABRE).

Incidents are included for the year in which they were reported, even if the investigation is not yet complete, as the investigation into some suspected viral TTIs can take several months.

During 2010, 48 suspected TTI incidents were reported by Blood Services and hospitals throughout the UK. A number of ATRs (over 50) were reported and investigated which did not meet the criteria for TTI, either because there was no evidence of infection in the recipient or the packs or because an alternative source of infection was identified. Some of the English cases were reported to the NHSBT/HPA Epidemiology Unit only and not to SHOT. It is recommended that such reactions be reported to SHOT and it is likely that most cases could be recorded as febrile reactions.

No incidents were confirmed as TTIs according to the above definition. A total of 39 investigations were concluded as not TTI, including 2 hepatitis B virus (HBV) incidents, 5 hepatitis C virus (HCV), 1 human immunodeficiency virus (HIV), 1 parvovirus and 30 bacterial incidents.

There were 3 undetermined bacterial TTI investigations in 2010.

In the first case, 1 unit of red cells was transfused into a patient following a lower limb amputation. Approximately 1 hour after the start of the transfusion the patient developed tachycardia, chest and abdomen pain, and a very slight temperature rise to 37.4ºC. The patient was on clarithromycin at the time of the transfusion and no additional antibiotics were given after the reaction, from which the patient recovered quickly. Blood cultures taken 2 days after the transfusion reaction were negative. *Bacillus cereus* was cultured from the remains of the red cell unit at the microbiology laboratories of both the hospital and the Blood Service, and these isolates were indistinguishable by molecular typing. However, it appears that the pack was sampled using a needle directly through the pack and the pack was leaking on arrival at the Blood Service. Samples from the donor taken after arm cleansing were negative. It was

therefore difficult to establish whether the bacteria entered the pack prior to transfusion or whether it was introduced during the microbiological sampling. Bacillus is a ubiquitous environmental organism and therefore, although unlikely to be a TTI, both scenarios are possible.

In the second case a patient received 2 units of red cells and 1 unit of platelets, after which the patient collapsed with hypotension, tachycardia and pyrexia. Blood cultures from the patient grew viridans streptococci. However, the empty transfused packs were discarded locally and were therefore unavailable for further investigation.

The third case involved 1 unit of apheresis platelets transfused to a patient who suffered a reaction within 10 minutes of completion of the transfusion. This initiated a recall of associated components (2 additional apheresis platelet components) that had been issued to two different hospitals. Clinical follow up of all 3 patients confirmed that transfusion related adverse reactions occurred in all 3 patients. At notification of this transfusion reaction, BacT/ALERT was negative for this component and was negative at completion of testing. Testing was repeated and extended for 7 days with negative results. Bacteriology investigations were instigated locally at two of the hospitals and both identified *Staphylococcus aureus* from the platelet residues, as well as other microbes that did not concur. Bacteriological investigations by the Blood Service on returned residues did identify bacteria but not *S. aureus*. BacT/ALERT was subsequently challenged with eight different isolates of *S. aureus* and all were detected. Samples of the bacteria identified by the hospitals were forwarded to a reference laboratory, which reported that the *S. aureus* identified by the two hospitals were similar but not identical. Review of the previous donation history of the donor indicated that the donor had been implicated in previous suspected transfusion reactions. On review, these previous investigations had revealed no evidence of bacterial contamination or any HLA-related issues with the recipients. There was no evidence of anti-IgA, HLA or platelet antibodies, although a granulocyte antibody was detected. Although bacterial contamination cannot be completely excluded, it is more likely that the cause of the transfusion reactions was the presence of a granulocyte antibody in the donor.

Six incidents reported in 2010 are pending complete investigation (1 CMV, 1 HBV, 2 HCV, 1 HIV and 1 bacterial case).

Confirmed incidents

There were no confirmed TTIs reported in 2010.

Other incidents

Near miss

There were 3 near miss incidents reported in 2010. In 2 separate incidents *S. aureus* was isolated from 2 unissued apheresis platelets after visible clumps/aggregates were noted in the packs, 1 at 3 days and 1 at 5 days. Neither donor had evidence of Staphylococcus species post arm cleansing. Both donors were therefore returned to the panel. In the third incident, organisms initially identified as *Klebsiella oxytoca* were isolated from an apheresis pack returned to the Blood Service by the hospital after it was noticed the contents of the pack looked 'odd'. On return, a large aggregate was observed in the pack with no evidence of holes or other damage to the pack. After further investigation at the Health Protection Agency reference laboratory the organism was identified as *Raoultella planticola*, a close relative of *Klebsiella*. Samples from the donor did not show Klebsiella-like organisms pre or post cleansing.

Investigations reported as pending or undetermined in 2009

There were 3 investigations reported as pending in 2009 (1 Human T-cell lymphotropic virus (HTLV), 1 HBV and 1 HCV). The reported HTLV infection was not confirmed and the investigation closed. In both the HBV and HCV cases no donor was found to have evidence of infection, and they were concluded as not due to TTI.

One HIV incident reported as undetermined in 2009 has now been completed. The last remaining donor was found to have no evidence of infection and therefore this incident was not a TTI.

Cumulative data

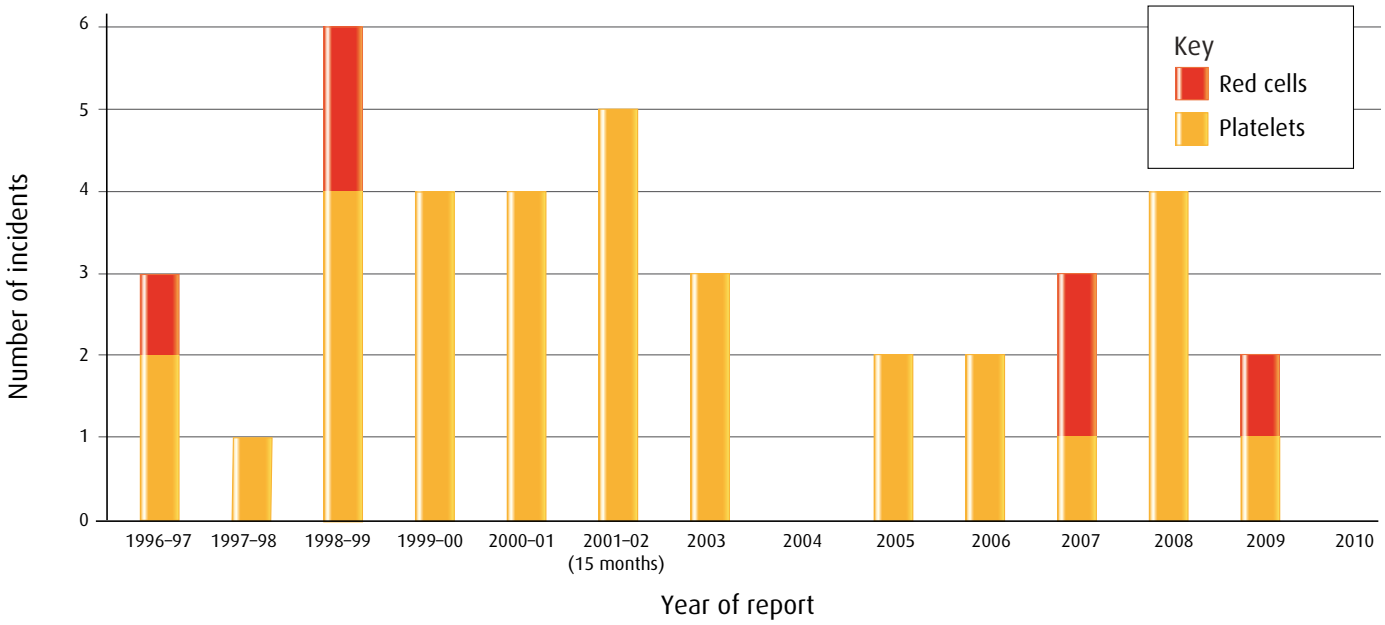
Bacterial TTIs

Since 1996, 40 bacterial TTI incidents have been confirmed, involving a total of 43 recipients (see Figure 18 and Table 48), 11 of whom died (death due to infection or in which transfusion reaction was implicated). A total of 33 incidents have related to the transfusion of platelets, whereas only 7 have related to the transfusion of red cells.

In Figure 18:

- The histogram shows the number of incidents, not infected recipients identified. For 2 incidents in 2008, and 1 in 2009, 2 infected recipients were identified in each incident.
- In 2004 there was a further incident (not included in Figure 18) involving the contamination of a pooled platelet pack contaminated with *S. epidermidis*. This incident did not meet the TTI definition as transmission to the recipient, although likely, could not be confirmed.

Figure 18
Number of bacterial TTI incidents, by year of report and type of unit transfused (Scotland included from 10/1998)



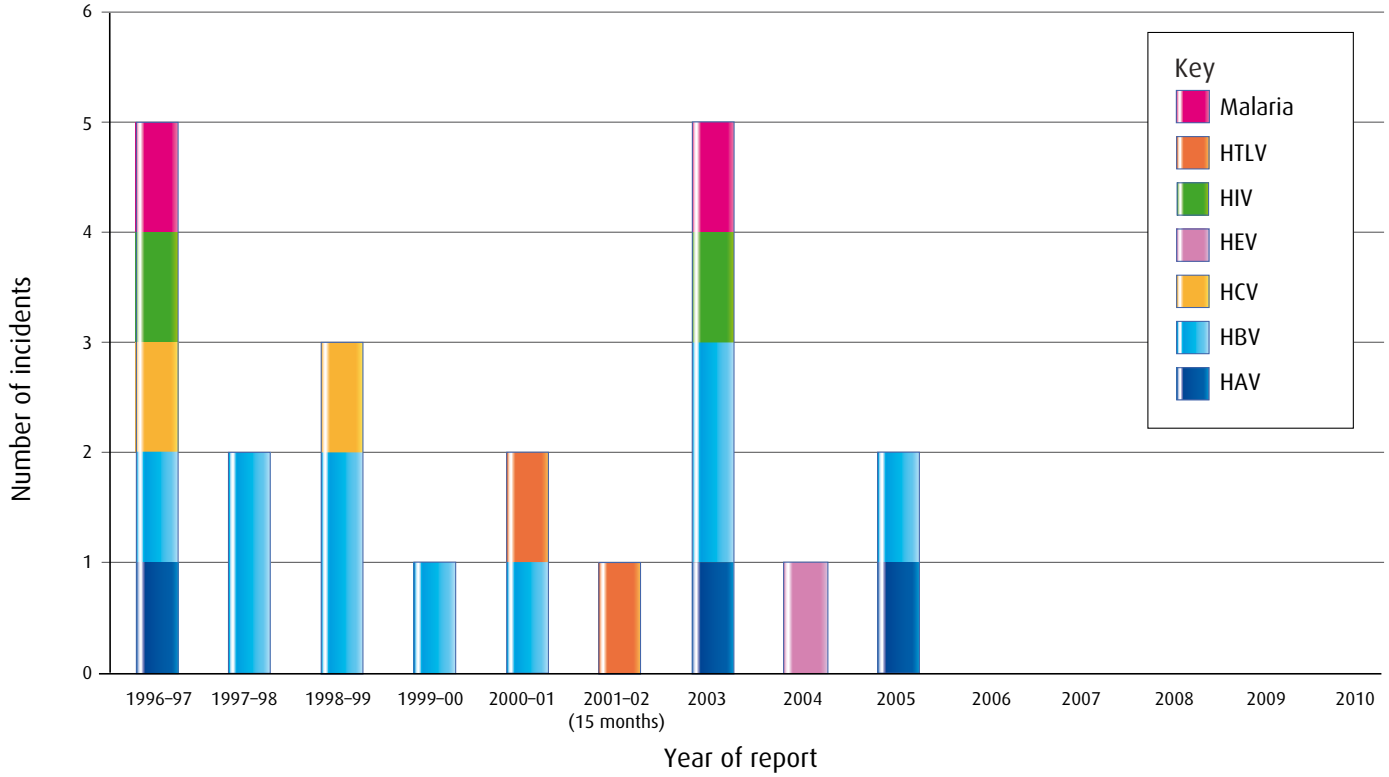
Viral and parasitic TTIs

Since 1996, 22 confirmed incidents of transfusion-transmitted viral and parasitic infections have been reported, involving a total of 25 recipients (see Figure 19 and Table 48); 1 incident resulted in a fatal transfusion reaction (malarial transmission). There have been no confirmed transfusion-transmitted viral or parasitic infections in recent years – the last confirmed incident was in 2005. Three of the incidents were related to the transfusion of platelets, including the 2005 hepatitis A virus (HAV) incident, while the remaining 19 incidents were related to the transfusion of red cells.

In Figure 19:

- The year of transfusion may have been many years prior to the year in which the case is investigated and reported in SHOT because of the chronic nature of some viral infections. The figure shows the number of incidents, not infected recipients identified. For 1 incident in 1996–97 (HIV) and 1 in 1999–2000 (HBV), 3 and 2 recipients were identified, respectively.
- The 2 HIV incidents were associated with anti-HIV negative/HIV RNA positive donations, i.e. window period donations. A third window period donation in 2002 was transfused to an elderly patient, who died soon after surgery. The recipient's HIV status was therefore not determined and not included in Figure 19.
- No screening was in place for the following TTIs at the time of transfusion: HAV, hepatitis E virus (HEV) and HTLV.

Figure 19
Number of viral and parasitic TTI incidents, by year of report and infection type (Scotland included from 10/1998)



Variant Creutzfeld Jakob Disease (vCJD)

There were no vCJD investigations in 2010.

To date there have been 4 incidents involving the transmission of vCJD/prion infection via red cell transfusion. Reporting of suspected vCJD transmissions differs from that of other infections: the cases reported were among a small group of recipients who were under active surveillance because they had received non-leucodepleted RBCs between 1996 and 1999 from blood donors later diagnosed with vCJD.

Since 1997, the UK Blood Services have introduced a number of precautionary measures:[1]

- Leucodepletion of all blood components (1999).
- Use of methylene-blue virally inactivated FFP (MB-FFP) obtained outside the UK for children under 16 years old (2002).
- Importation of plasma for fractionation (1998).
- Imported solvent detergent treated FFP (SD-FFP) for adult patients with TTP (2006).
- Exclusion of donors who have received a blood transfusion in the UK since 1980 (2004).

Work to develop a test for vCJD is at a very early stage of development. The UK Blood Services are involved in the work to develop further a possible test. However, there is currently no screening test for vCJD available for use in blood donors.

Table 48
Number of confirmed TTI incidents, infected recipients and outcomes (death, major morbidity, minor morbidity) in the UK between October 1996 and December 2010 (Scotland included from October 1998)
NB No screening in place for the following TTIs at the time of transfusion: HAV, HEV, HTLV, vCJD/prion

Infection	No. of incidents	No. of infected recipients	Death due to, or contributed to by, TTI	Major morbidity	Minor morbidity
Bacteria	40	43	11	28	4
HAV	3	3	0	2	1
HBV	10	11	0	11	0
HCV	2	2	0	2	0
HEV	1	1	0	0	1
HIV	2	4	0	4	0
HTLV1	2	2	0	2	0
Malaria	2	2	1	1	0
Prion	1	1	0	1	0
vCJD	3	3	3	0	0
Total	**66**	**72**	**15**	**51**	**6**

COMMENTARY

In 2010 there were no proven reports of TTI. This reflects the continuing high working standards and improvements based on the learning outcomes from previous investigations into contamination incidents.

Currently the greatest risk of TTI is associated with bacterial contamination, although there is likely to be under-reporting of both viral and bacterial incidents. A BCSH guideline on the management of ATRs is currently in preparation (expected 2011).

If bacterial contamination is suspected, staff should report the incident to the Blood Services as soon as possible, in order to facilitate the return of implicated packs and the recall of any associated units. The Blood Services provide comprehensive bacterial testing and where isolates are available from the recipient and pack will arrange typing of strains. However, if sampling the pack locally, attention should be paid to the sampling and storage of implicated units or their residues to avoid contamination of the pack. It is suggested that an unused administration port is swabbed with 70% ethanol and left to dry before inserting a sample site coupler spike with needle injection site or equivalent into the port. This will enable the bag to be sampled with a sterile hypodermic needle and syringe, but still maintain the integrity of the bag. The coupler spike should also be swabbed, as before, prior to sampling. Where possible, any organisms isolated in local laboratories should also be returned to the Blood Service reference laboratory to allow the completion of the investigation. The investigation of possible TTIs forms part of the quality and governance framework.

If viral or parasitic contamination is suspected staff should, before reporting, attempt to ensure that the infection is confirmed and was not present prior to the transfusion. For example, testing for antibodies to hepatitis B core in samples taken prior to transfusion can help to rule out reactivation of past HBV infection in immunocompromised patients. As the risks of TTI are so low, other identified possible sources of infection should be investigated without waiting for the outcome of the Blood Service investigation.

Guidance and reporting forms for suspected bacterial, viral or parasitic TTIs for hospitals served by NHSBT can be found at http://www.blood.co.uk/hospitals/library/request_forms/aer/. For other services please contact the local blood supply centre.

Strategies to reduce the bacterial contamination of blood components are under continual review. Most of the UK Blood Services already screen platelet donations for bacterial contamination and this was introduced in NHSBT in early 2011.

It should be noted that bacterial screening is unlikely to prevent all transmissions and the current high standards of collection, processing and vigilance should be maintained.[2]

The current estimated risks of transmission of HBV, HCV, HIV and HTLV via blood transfusion are low (1.50 per million donations for HBV, 0.01 per million for HCV, 0.20 for HIV and 0.06 for HTLV-1).[3]

Learning points

- If sampling packs for bacterial testing, use ports rather than breaching the pack to minimise environmental contamination of the pack post transfusion.
- Retain suspected bacterially contaminated packs even if near empty for return to the Blood Service as these can be washed out and the residue cultured.
- Testing for antibodies to hepatitis B core in samples taken prior to transfusion can help rule out reactivation of past HBV infection in immunocompromised patients.

Recommendations

- Attention should be paid to the sampling and storage of implicated units or their residues to avoid sampling or environmental contamination of the pack.

  Action: Hospital microbiology laboratories

- Even if TTI is excluded in a case of ATR, the case should still be reported to SHOT as an ATR.

  Action: HTTs, clinicians

- Clinicians investigating suspected viral TTIs should explore all possible risk exposures in parallel with the Blood Service investigations, in order to determine the patient's most likely source of infection. This includes checking records and testing samples taken prior to the implicated transfusion(s) to check that the recipient was not infected prior to transfusion.

  Action: Clinicians, UK Blood Services

For active recommendations and an update on their progress, please refer to the SHOT website.

19. Autologous Transfusion

Definition

Any adverse event or reaction associated with autologous transfusion, including intraoperative and postoperative cell salvage (washed or unwashed), acute normovolaemic haemodilution (ANH) or preoperative autologous donation.

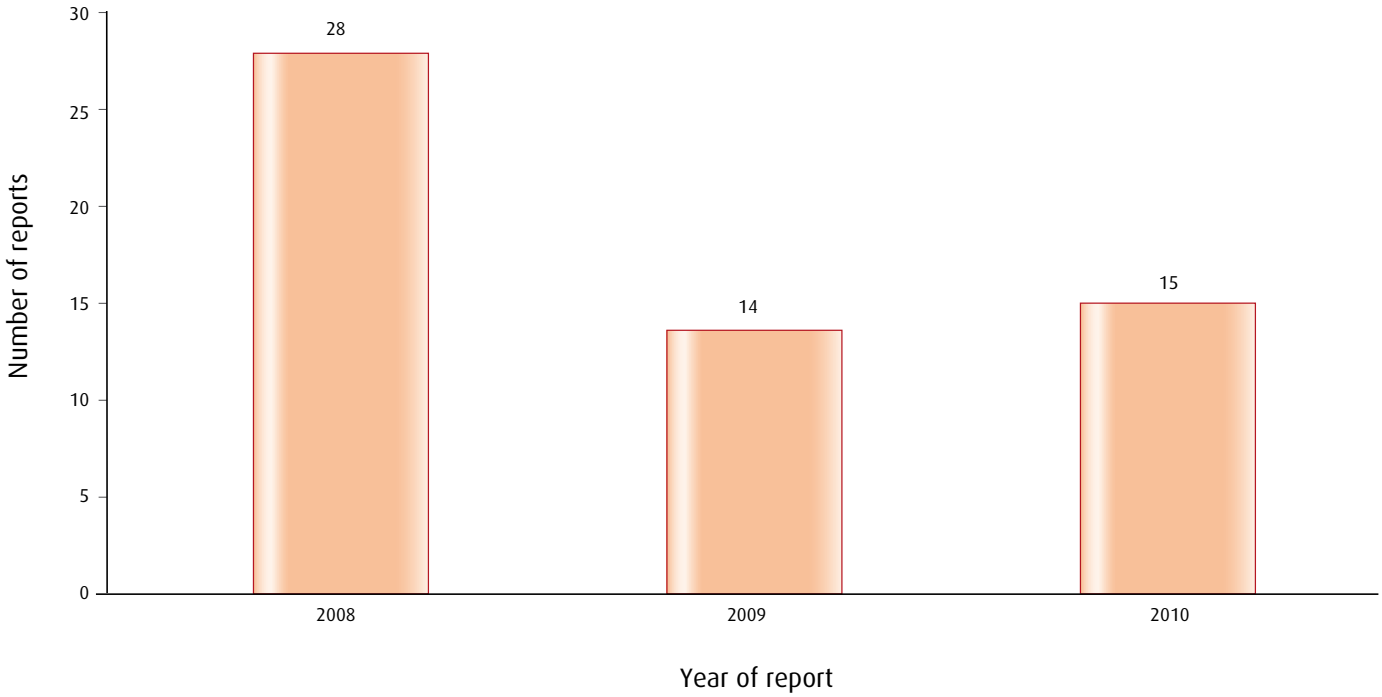
DATA SUMMARY

Total number of cases	**15**	*Implicated components*		*Mortality/morbidity*	
		Red cells	**15**	Deaths due to transfusion	**0**
		FFP	**0**	Deaths *probably/likely* due to transfusion	**0**
		Platelets	**0**	Deaths *possibly* due to transfusion	**0**
		Other (granulocyte)	**0**	Major morbidity	**1**
		Unknown	**0**		

Gender		*Age*		*Emergency vs. routine and core hours vs. out of core hours*		*Where transfusion took place*	
Male	**10**	≥18 years	**15**	Emergency	**1**	A&E	**0**
Female	**5**	16 years to <18 years	**0**	Routine	**13**	Theatre	**0**
Not known	**0**	1 year to <16 years	**0**	Not known	**1**	ITU/NNU/HDU/recovery	**0**
		>28 days to <1 year	**0**				
		Birth to ≤28 days	**0**	In core hours	**10**	Wards	**0**
		Not known	**0**	Out of core hours	**5**	Community	**0**
		Total	**15**	Not known	**0**	Outpatient/day unit	**0**
						Not known	**15**

The number of reports submitted under this category remains unchanged and as yet there are no data on the number of autologous procedures in the UK. There were no reports received during this reporting period relating to adverse events while undertaking ANH or preoperative autologous donation (PAD). Both these techniques are rarely undertaken and their use is not routinely recommended. The 15 reports were submitted by 9 different Trusts/Health Boards.

Figure 20
Number of autologous adverse events by year



Adverse events by type of autologous transfusion

Intraoperative cell salvage (ICS), 8 events; postoperative cell salvage (PCS), 5 events; combined, 2 events.

Adverse events by specialty

Orthopaedic, 7 events; cardiac, 3 events; urology, 2 events; neurosurgery, vascular and obstetrics, 1 event each.

Incidents

PCS

Patients in this category had varying reports of rigors, dyspnoea, hypertensive episode and feeling unwell and these 5 cases were all recorded as reactions as opposed to adverse events.

Case 1

Lack of patient identifiers on cell salvaged units

Two patients had undergone a total hip replacement (THR) and both were having postoperative cell salvage. The patients had units 'spiked' at the same time and both patients had rigors, temperature increase and vomiting within 15 minutes of the start of the unit. The reporter could not rule out the units were transposed as in both cases the drains were removed from the patient and taken to a treatment room to be primed through the giving set.

Learning point

- All cell salvaged units should be labelled with the patient core identifiers to reduce the risk of error on reinfusion. The autologous transfusion label has been designed by the UK Cell Salvage Action Group and supplied by the manufacturers to allow these criteria to be met.

Combined

The 2 combined incidents occurred in cardiac cases and reported clots in the reservoirs and these are recorded as adverse events.

ICS

These included 4 reactions, 3 adverse events and 1 machine failure. The machine failure was due to a faulty switch, which led to loss of suction. The adverse events were:

- 1 × thrombus formation, which occluded the reservoir
- 1 × blood collected, which was stored in fridge
- 1 × severe coagulopathy following reinfusion of 1110 mL of salvaged blood following an emergency Caesarean section. This case also received the following units of blood: 11 RBCs, 4 FFP, 4 cryoprecipitate, 1 platelets and 7.2 mg rVIIa, and was admitted to ITU.

In the reaction category:

- 1 × hypotension using an unwashed ICS system
- 3 × hypotension, all using leucodepletion filters and ACD as the anticoagulant.

The last three SHOT reports have all included hypotensive reactions involving ICS, the use of leucodepletion filters and the use of acid citrate dextrose (ACD) as the anticoagulant. This phenomenon has been recognised and noted in the Association of Anaesthetists Great Britain and Ireland (AAGBI) safety guideline on cell salvage[1] and in the MHRA 'One Liner'. [2] While an attempt has been made to analyse this phenomenon further, it appears that there are a number of other issues that were reported in the 2008 SHOT report, namely:

- The use of bedside leucocyte depletion filter (LDF), which is known to cause hypotension when used with allogeneic blood as previously recognised.[3]
- These patients may be hypovolaemic and therefore more susceptible to the vasoactive cytokines reinfused.
- All patients experienced transient but significant hypotension corrected by the cessation of infusion and/or vasopressors.
- No long-term sequelae of this hypotension were noted.

It is important that this is recognised as a possible adverse reaction and treated by discontinuation of the infusion of the salvaged red cells and appropriate vasopressors.

Learning point

- Monitoring of patients during the transfusion is as important for the reinfusion of red cells collected by ICS or PCS as it is for allogeneic red cells.

COMMENTARY

The number of cases reported of cell salvage related adverse events and reactions remained low, but without knowledge of the number of annual procedures in the UK these numbers cannot be interpreted.

Recommendation

- All ICS- and PCS-related adverse events and reactions should be reported to SHOT.

  Action: Cell salvage practitioners, blood conservation coordinators, HTCs

For active recommendations and an update on their progress, please refer to the SHOT website.

20. Paediatric Cases

Definition

Paediatric cases comprise all those occurring in patients under 18 years of age.

Paediatric cases 2010

This chapter analyses the data on paediatric cases from the other chapters in this annual report. All the cases are also included in the data in their respective chapters. All children <18 years of age are included and have been subdivided by age groups (neonates ≤28 days, infants >28 days and <1 year old, and children <16 years) because each of these has recommendations regarding blood components.

Table 49
Summary of paediatric cases 2010

Category of case	No. ≤28 days	No. >28 days to <1 year	No. 1 to <16 years	No. 16 to <18 years	Total paediatric cases
IBCT (total)	**8**	**7**	**15**	**2**	**32**
IBCT clinical	2	0	0	0	2
IBCT laboratory	4	4	7	0	15
SRNM (total)	2	3	8	2	15
Irrad/CMV negative	*1*	*2*	*4*	*2*	*9*
MB-FFP/SD-FFP/MB-cryo	*0*	*1*	*4*	*0*	*5*
Others	*1*	*0*	*0*	*0*	*1*
WBIT	0	0	0	0	0
IBCT misc.	0	0	0	0	0
I&U	**1**	**0**	**9**	**2**	**12**
HSE	**2**	**4**	**5**	**1**	**12**
Anti-D Ig related	**0**	**0**	**2**	**4**	**6**
ATR	**3**	**6**	**35**	**9**	**53**
HTR	**0**	**0**	**1**	**0**	**1**
TRALI	**1**	**0**	**0**	**0**	**1**
TACO	**0**	**0**	**0**	**0**	**0**
TAD	**0**	**3**	**1**	**1**	**5**
PTP	**0**	**0**	**0**	**0**	**0**
TA-GvHD	**0**	**0**	**0**	**0**	**0**
TTI	**0**	**0**	**0**	**0**	**0**
Autologous (cell salvage)	**0**	**0**	**0**	**0**	**0**
Total	**15**	**20**	**68**	**19**	**122**

Near miss	**12**	**1**	**26**	**2**	**41**
RBRP	**0**	**1**	**1**	**0**	**2**

NB Near miss and RBRP numbers are shown separately as they are not included in the overall reporting figures.

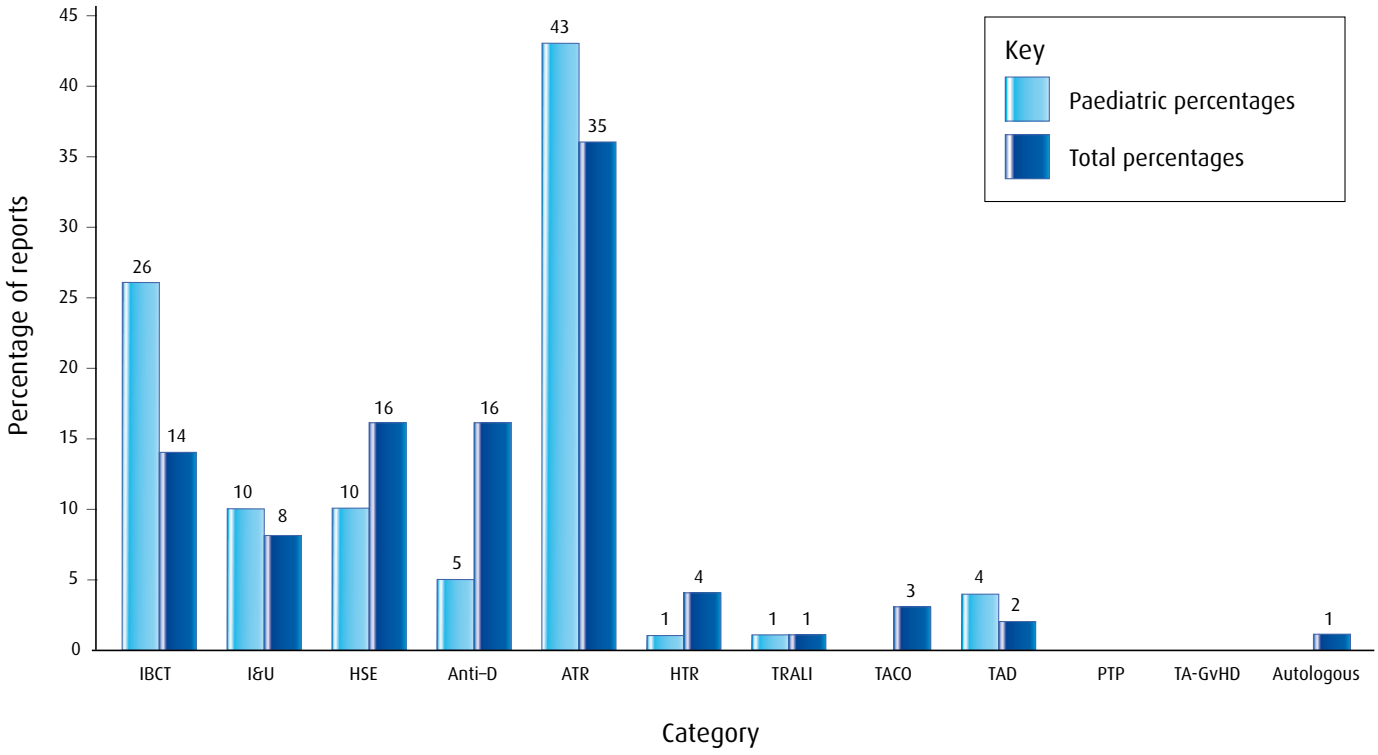
Introduction and overall trends

As has been highlighted in previous reports and by Stainsby *et al*. (2009),[1] there are a disproportionate number of cases in the paediatric age group, reflecting both clinical and laboratory issues. For 2010, paediatric reports were 122/1464 (8.3%) of the total, similar to previous years. If near miss and RBRP cases are added, paediatric cases are 165/2464 (6.7%). Of 122 paediatric reports 35 (29%) were in infants <1 year of age, of whom 15/35 (43%) were neonates ≤28 days old. The pattern of reports across categories is different for paediatrics as compared with the total, with a higher proportion of paediatric IBCT in particular (see Figure 21).

Error-related reports (IBCT, HSE, I&U and anti-D) were 62/122 (51%) of all paediatric reports and 22/35 (63%) of those in infants <1 year. Infant reports were 22/62 (35%) of all paediatric error reports and although the number of paediatric error reports overall has changed little over the last 3 years, reports in neonates ≤28 days decreased from 19 in 2008 to 11 in 2010. A total of 32 out of 62 (52%) paediatric errors originated primarily from the laboratory (26 IBCT, 3 HSE, 2 I&U and 1 anti-D). Of all paediatric reports 26% were laboratory errors, similar to 2009 (30% excluding anti-D).

The number of ATR reports in children has been showing a year-on-year increase, this year comprising 53/165 (32%) cases (compared with 25 in 2008 and 37 in 2009).

Figure 21
Percentages of paediatric and total reports in each category



Error-related reports *n* = 62

Incorrect blood component transfused *n* = 32

IBCT – clinical *n* = 2

There were only 2 reports; both related to sick neonates who subsequently died unrelated to the transfusion, and both are examples of ongoing problems with collecting the incorrect blood for neonatal emergencies. One report involved collection of the adult emergency unit rather than the paediatric emergency unit and the second, collection of crossmatched rather than emergency blood.

Case 1

Confusion between emergency blood and crossmatched blood

A preterm baby required an emergency transfusion at 6 days of life and should have been given O RhD negative emergency blood from the satellite fridge. The nurse inadvertently collected an O RhD negative unit that had been issued to an obstetric patient on the delivery suite. The blood group and CMV status of the unit was checked with another nurse, but they did not notice that the tag on the unit had a compatibility label on as opposed to an emergency blood label.

IBCT – laboratory error *n* = 15

There were increased numbers of paediatric laboratory error reports in 2010. Eight were from infants <1 year of age, with 3 relating to the laboratory not taking into account maternal antibodies when issuing blood for young infants, and 2 in infants 4–5 months old issued paedipaks without serological testing. Two involved RhD errors, 1 in RhD grouping and 1 where an RhD negative neonate was given RhD positive red cells. In the final infant report, paedipaks (CMV negative, irradiated) were issued for neonatal ET instead of neonatal exchange red cells (see Chapter 7, page 28, for further details of laboratory cases).

Case 2

Incorrect neonatal pre-transfusion compatibility testing procedures

A G&S/DAT request was received in the laboratory on a newborn preterm baby with a low Hb, and later that day blood was requested. The same request was repeated, twice, 2 days later. The first two requests were treated as EIs and the third request was treated as a crossmatch. However, the mother of the baby had an antibody and therefore the blood for the infant should have been crossmatched on all three occasions.

In the 7 reports in children ≥1 year old, 1 was a 15-month-old child for whom blood was issued without an antibody screen as the laboratory scientist had written on the request form that it was for a baby <3 months old. In 3 reports RhD positive platelets were given to RhD negative recipients, 2 female and 1 a male 1-year-old with a severe congenital immunodeficiency. Three reports involved issue of red cells following inadequate laboratory procedures: to a post bone marrow transplant (BMT) patient by EI only, to the ward prior to reading the crossmatch result and after crossmatch but with unauthorised group and screen results, missing a positive antibody screen.

Case 3

Example of laboratory error not detected by ward staff

A single unit of O RhD positive platelets was issued for an O RhD negative 2-year-old girl as a routine request. The RhD mismatch was not considered a problem by the laboratory scientist on-call, as 'this was common practice' in their previous hospital (an adult hospital). The nursing staff did not question the discrepancy and proceeded to transfuse the unit. The error was subsequently detected by laboratory staff and the child was prescribed anti-D Ig.

IBCT–SRNM *n* = 15

The number of paediatric SRNM reports was down in 2010 (25 reports in 2009). Eleven were defined as laboratory errors, of which 5 related to MB-plasma, 4 to CMV negative components, 1 was lack of provision of irradiated granulocytes by NHSBT and 1 was failure to provide platelet antigen negative platelets where the mother was suspected of having anti-platelet antibodies despite this having been documented on the request form. Three of the MB reports related to MB-cryoprecipitate, 1 relating to the transfusion of non-MB-cryoprecipitate stock to 4 separate paediatric patients. For the CMV negative components, 2 were age-related CMV requirements for infants <1 year, and 2 in older children with haematological diagnoses.

All the 4 clinical SRNM cases related to lack of proper requests for irradiated blood, and the lack of requesting was not specifically related to the patient being a child.

Case 4

Lack of communication between clinicians and laboratory

A baby was admitted to a paediatric ward for a top-up transfusion having previously received an IUT and an ET. The haematologist advised the ward of the need for irradiated blood. Blood was prescribed and the need for irradiation documented on the prescription pathway but not communicated with the transfusion laboratory. Non-irradiated blood was issued and transfused. The same thing happened a second time, and the error was only noticed by a nurse at a subsequent transfusion.

I&U transfusion *n* = 12

There were 5 reports of over-transfusion of children: 3 due to incorrect prescription and 2 to incorrect administration of red cells. One of these was to a neonate and the other patients ranged in age from 1 to 6 years, but in all cases the errors related to inadequate attention being paid to ensure safe blood administration to this age group.

Case 5

Administration error resulting in transfusion of entire paedipak

A 24-day-old baby in the neonatal unit was prescribed a transfusion of 14.3 mL of red cells. The baby's Hb rose from 9.7 g/dL pre transfusion to 20.0 g/dL post transfusion. On examination of the paedipak it was noted the bag was empty, suggesting that the baby had received the full 50 mL paedipak in error. This was felt to be due to the blood having been given via a neonatal Y blood-giving set and problems with the closure of the roller clamp, in the line connected to the roller clamp.

Case 6

Prescription error on PICU

A 6-year-old ventilated patient received 2 adult units of blood. The blood was prescribed by units not millilitres required. Hb pre transfusion 7.7 g/dL, post transfusion 13.8 g/dL (just above the top end of the age-related normal range of 13.5 g/dL). Calculation based on weight (30 kg) gave an increase to 11 g/dL from 270 mL of transfusion.

If this had been a patient with sickle cell disease, over-transfusion to this level could have resulted in significant morbidity.

The remaining 7 reports were not specifically related to the age of patient. They included 3 where either red cells or platelets were transfused inappropriately on the basis of an incorrect result. Two related to near-patient testing: 1 where a glucometer was used inappropriately to monitor the Hb (see Chapter 8) and 1 where a HemoCue® result may have led to over-transfusion of a 16-year-old with a postpartum haemorrhage. For a 3-year-old cardiac patient with significant bleeding and a high INR, FFP was given twice unsuccessfully to reverse a warfarin effect, contrary to BCSH guidelines,[2] before giving prothrombin complex concentrate. Finally, there were reported delays in availability of blood in A&E for a 16-year-old victim of an RTA.

HSE *n* = 12

Most of the paediatric HSE reports did not relate specifically to the recipients being children. There were 4 reports where red cells were not transfused within the accepted time out of temperature-controlled storage and this occurred among recipients aged between 9 days and 11 years. There were 3 other red cell cold chain errors and a 17-year-old received platelets over 1 hour and 2 minutes, against the Trust policy of 30 minutes. There were 3 technical administration errors, including a pump misprogrammed such that a 14-year-old received a unit of red cells over 1 hour rather than 2 as prescribed, and a further report associated with neonatal transfusion using a Y giving set.

Case 7

Neonate fails to respond to transfusion of red cells

A top-up transfusion of 14 mL of RBCs administered to a neonate failed to increase their Hb, despite receiving a second aliquot of 14 mL. On investigation it is thought that the roller clamp between the Y-connection and the syringe driver may not have been fully engaged, resulting in red cells being drawn back into the red cell unit.

Finally, there was a report where granulocytes for a 2-year-old were decanted into a sterile receptacle following difficulties with accessing the bag (see Chapter 9).

Anti-D Ig related events *n* = 6

There were 6 reports in pregnant paediatric patients, 2 of whom were under 16 years old. Apart from the age, there were not specific paediatric-related issues.

Transfusion reactions *n* = 60

ATR *n* = 53

The number of paediatric ATRs reported continues to steadily increase and comprises 10% of all ATR reports to SHOT. The proportion of reports for each component type was broadly similar to last year, with reactions to red cells 28/53 (53%), platelets 17/53 (32%) and plasma 8/53 (15%), which was slightly increased. The striking number of platelet reactions was highlighted in 2008 (18/25, 75% of paediatric ATRs), but these are similar in 2010 and it is red cell ATRs that make up the majority of the increase in paediatric ATR reports.

Most paediatric ATR reports were in age group ≥1 year, with only 9/53 (17%) in infants <1 year, including 3 from neonates. It is notable that in children from 1 year to <16 years, 21/31 (68%) reports where a diagnosis was given were from patients with malignancies and 26/31 (84%) were from haematology/oncology patients, including those with haemoglobinopathies. Two of the neonatal cases could not be classified according to type of reaction, illustrating the difficulty in recognising transfusion reactions in this often clinically unstable group of patients.

Case 8

Diagnostic difficulty in a preterm neonate

A 10-day-old preterm baby transfused with red cells developed profound apnoea and bradycardia during the transfusion, requiring bagging and oxygen. The transfusion was stopped and the red cells returned to the laboratory. The baby was DAT negative and a crossmatch was compatible. The baby was also unwell with problems to do with prematurity and it was not clear whether the symptoms should be attributed to the transfusion or not. The baby recovered after 2 hours and 55 minutes.

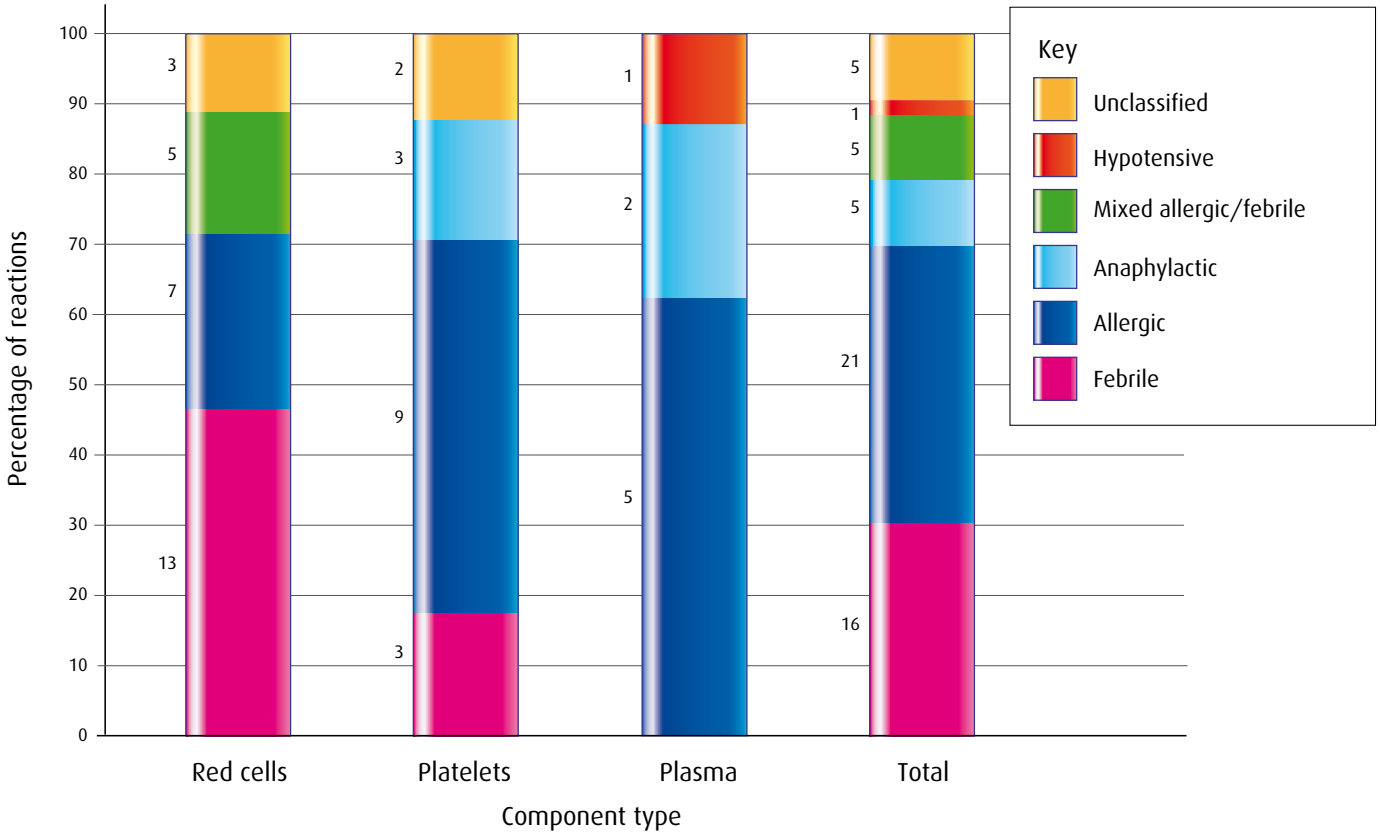
Paediatric reactions were classified as described in Chapter 11. Of the 48 that could be classified, 6 (13%) were severe, 27 (56%) were moderate and 15 (31%) were mild. The proportion of severe reactions was almost identical to the proportion of severe ATR in overall reports. However, there was a higher proportion of mild reactions in the paediatric group than overall (see Chapter 11). There were 5 anaphylactic reactions: 3 to platelets and 2 to MB-FFP.

The types of reactions and associated components are shown in Table 50 (see Chapter 11, page 73, for total numbers of reports in each category). The table illustrates that the majority of febrile reactions reported were to red cell transfusions, allergic reactions followed all types of components and anaphylactic reactions were restricted to platelets and plasma. Figure 22 illustrates the percentage of each type of reaction by component: the most common type of report for platelets and plasma was allergic, whereas for red cells it was febrile.

Table 50
Type of reaction for each component for paediatric reports

Reaction	Red cells	Platelets	Plasma	Total
Febrile	13	3	0	16
Allergic	7	9	5	21
Anaphylactic	0	3	2	5
Mixed allergic/febrile	5	0	0	5
Hypotensive	0	0	1	1
Unclassified	3	2	0	5
Total	**28**	**17**	**8**	**53**

Figure 22
Number and percentage of reactions by component type for paediatric reports



Of the 15 platelet reactions in the <16 year age group, 3 were stated to have been pooled platelets (to haematology/oncology patients), illustrating continued use of pooled platelets in this age group. Of the reactions to plasma, 1 was to cryoprecipitate and the rest to FFP, including both MB-FFP and SD-FFP.

Case 9

Severe reaction to prophylactic FFP

A 15-year-old patient was given FFP to correct a coagulation abnormality prior to a lumbar puncture. After approximately 50 mL of the third unit the patient developed facial rash, swelling, orbital oedema and tongue swelling with peripheral mottling. The patient was treated with antihistamines, steroids and 2 doses of IM adrenaline. The patient was admitted to HDU overnight and required inotropes for hypotension. The patient made a full recovery within 24 hours.

This case illustrates a severe reaction to FFP given for prophylaxis and therefore the need to scrutinise the appropriate use of prophylactic plasma transfusions.

HTR *n* = 1

There was only 1 paediatric report, in an alloimmunised patient with sickle cell disease, who died as a result of a hyperhaemolytic transfusion reaction (see Chapter 12, page 81).

Learning point

- Hyperhaemolysis is an uncommon but well-documented serious complication of transfusion in sickle cell disease in which there is destruction of both autologous and transfused red cells. If possible, further transfusion should be avoided since this may exacerbate the haemolysis and lead to a protracted clinical course or even death. The use of IVIg and/or steroids should be considered as a means of correcting the anaemia.

TRALI *n* = 1

Case 10

Difficulty in excluding TRALI in preterm neonate

A case of possible TRALI was reported in a 16-day-old extremely preterm baby who was ventilated and unwell, having needed high airway pressures for ventilation. Three hours 25 minutes following the start of a red cell transfusion the baby had an acute oxygen desaturation and fresh blood was aspirated from the endotracheal tube. The baby required high-frequency oscillatory ventilation and improved rapidly within 24 hours.

Although this was reported as possible TRALI, on expert review it was felt more likely to be a severe pulmonary haemorrhage, a recognised complication for a neonate developing chronic lung disease. This case again illustrates the difficulties of distinguishing transfusion reactions from other clinical problems in sick preterm babies.

TAD *n* = 5

There were 3 infants <1 year (youngest 3 months old) and 2 older children, the first paediatric reports in this category. Three cases were following platelets and 2 following red cells. It is likely to be difficult to distinguish TAD from other transient changes in the respiratory status of sick neonates, and there were no reports in neonates ≤28 days old. A further paediatric case report is given in Chapter 15.

Case 11

An infant case of TAD

An 11-month-old child presented in A&E generally unwell for the past few months, pale and tachycardic. The child was anaemic and thrombocytopenic, with an Hb of 5.2 g/dL, platelets 10 × 10^9/L and a raised WCC. The child was admitted to the paediatric ward for a platelet transfusion and during the transfusion developed a productive cough with subcostal recession. There was a slight increase in the RR from 30 per minute to 36 per minute but no oxygen desaturation or other changes in vital signs.

TACO, PTP, TA-GvHD, autologous transfusion

There were no paediatric cases in these categories.

Near miss *n* = 41

Paediatric near miss cases were 4.8% (41/863) of total cases. Neonatal reports were 12/41 (29%) of paediatric near misses and nearly all the others were in children between 1 and <16 years old. Most cases were due to errors not specific to paediatric patients. However, 3 of the WBIT reports were associated with the recipients being neonates: 2 where twin cord samples were mixed up, and 1 where a baby's sample was labelled with the mother's details. Finally, a 4-month-old infant was issued a paedipak without age-appropriate serological testing.

RBRP *n* = 2

There were 2 RBRP cases: a name misspelling on addressograph labels and a date of birth discrepancy between the patient information system and the laboratory information system.

COMMENTARY

- There are repeated cases of poor understanding by laboratory staff of procedures for neonatal and infant pre-transfusion compatibility testing and the need to take into account maternal antibodies, emphasising the requirement for adequate laboratory staff competency in paediatric transfusion.

- There are ongoing reports of confusion among clinical staff over blood availability for neonatal emergency transfusions. Local policies and training should be instituted to reduce the risk of this error.

- There were 3 reports of non-MB cryoprecipitate being issued. MB cryoprecipitate became available for children <16 years in 2009 in order to provide pathogen-inactivated cryoprecipitate as well as FFP from overseas. Although not all hospitals use MB cryoprecipitate for children, failure to use it where it has been implemented constitutes an error.

- There were 5 reports of over-transfusion of children. This is an ongoing problem despite having been highlighted in previous SHOT reports and addressed in the BCSH (2009) guidelines on the administration of blood components.[3] The issue of prescribing by units rather than millilitres for children was also highlighted by the results of the 2010 National Comparative Audit (NCA) of red cell transfusion in neonates and children,[4] which reported that 39% of red cell prescriptions on paediatric wards were in units.

- The use of neonatal Y blood-giving sets was implicated in 2 reports, one each of over- and under-transfusion, highlighting the need to be sure that equipment for paediatric transfusions is appropriate for purpose and set up correctly, and that the volume delivered should be monitored regularly throughout the infusion.[3]

- The number of paediatric ATR reports continues to increase, particularly following red cell transfusions where the largest category of reports is febrile reactions; this is likely to be due to changed reporting patterns but requires ongoing monitoring. Anaphylactic reactions were reported to both platelets and FFP, emphasising the need to transfuse these components only where clearly indicated.

Recommendations

- The 2009 SHOT recommendation on the need for local consideration of the design of prescription charts to facilitate the correct prescription of blood component volumes and rates for children is re-emphasised this year following ongoing SHOT reports in 2010 and the results of the 2010 NCA demonstrating frequent prescription of red cells for children in units as opposed to millilitres.

  Action: RTCs, HCTs, HTTs, pharmacists

- Laboratory staff competency on the issues surrounding neonatal and infant pre-transfusion compatibility testing should be targeted during training, particularly given the relatively low frequency of paediatric work in many laboratories. The revised BCSH guidelines on compatibility testing will clarify the requirements for neonates.

  Action: HTTs, hospital transfusion laboratories, consultant haematologists with responsibility for transfusion

For active recommendations and an update on their progress, please refer to the SHOT website.

21. Near Miss Reporting

Definition

A near miss event refers to any error which, if undetected, could result in the determination of a wrong blood group or transfusion of an incorrect component, but was recognised before the transfusion took place.

SHOT has been collecting near miss events since 2000–01, and data have consistently shown that approximately 50% of these events occur at the sampling phase. A workshop was held in November 2006, following on from which two surveys were undertaken, the first of which analysed sample errors detected at 'booking in' and the second involved sample errors that were detected later in the process. The results of these surveys have been presented in the 2008 SHOT report, and a decision was then taken not to further analyse errors falling into the former category.

There is considerable overlap between the near miss reports submitted to SHOT and serious adverse events (SAEs) reported to the MHRA. Their analysis here is valuable in that they highlight potential weaknesses in the process of blood transfusion and often have the same root cause as the reported actual transfusion errors.

This year 921 near miss reports were received, of which 58 were withdrawn by the reporter since they constituted labelling errors that were detected during the 'booking in' process or wastage of components due to changes in the clinical condition of the intended patient. For consistency, the remaining 863 reports have been analysed in accordance with the categories previously used.

Table 51
Numbers of near misses according to category of incident

Category of incidents	No. of cases
Sample errors	409
Request errors	44
Laboratory procedural or testing errors	119
Laboratory component selection errors	100
Component collection/administration errors	50
Expired components available	29
Cold chain events	97
Others	15
Total	**863**

Sample errors *n* = 409

There were 386 cases due to WBIT. The remaining 23 errors related to samples being labelled incorrectly (omissions or errors in patient identifiers), which were not rejected at booking but were detected at a later stage in the process.

WBIT *n* = 386

Of 386 reports, the majority of samples were taken by a doctor, and in all but 4 cases these events could have been prevented by ID of the patient at the bedside at the time of blood sampling. Instead, reliance was placed on case notes, request forms or prescription charts that did not belong to the patient in question, for patient ID.

Table 52
Staff responsible for WBIT incidents

Staff responsible for taking sample	No. of reports
Doctor	170
Nurse	75
Midwife	55
Healthcare assistant	16
Phlebotomist	13
Medical student	2
Unknown/not stated	55
Total	**386**

Practices leading to WBIT

Examples of how incorrect patient ID occurred, which could have been prevented by ID of the patient at the bedside, include:

- Sample labelled by a second person away from the bedside.
- Incorrect patient record selected on PAS in A&E.
- Sample labelled with information from the incorrect prescription chart.
- Sample labelled with information from the incorrect request form.
- Sample labelled from the information given in the incorrect notes:
  - Wrong notes obtained from medical records on patient admission, 1 of which was only discovered when the patient entered the day case theatre.
  - Wrong notes selected by phlebotomist – patient was either in a different bed number than had originally been allocated or the notes had been filed against a different bed number.
  - Another patient's addressograph labels were filed in the notes that were used to identify the patient.

There were 4 cases where the error in patient identity could not have been detected by the phlebotomist:

- Identity theft: a young male arrived unconscious in A&E and a driving licence found in his wallet was used to identify him for blood samples. However, when his parents arrived it transpired that the driving licence belonged to his older brother.
- The records of 2 patients with the same name and date of birth had been merged within the Trust, only 1 of whom had a historic blood group.
- 2 cases where patients shared the NHS number with another patient.

Case 1

Incorrect patient record selected from PAS

During a trauma call, a doctor sampled the patient and gave the sample to a second person, verbally confirming the name and date of birth of the patient. This second person interrogated the PAS but selected a patient record with the same forename and family name but with a one digit difference in the date of birth, which was used to identify the sample.

Case 2

Patients identified by bed numbers only

A nurse was instructed to take a blood sample from the patient in Bed 2. She was given no documentation and continued to label the sample with the information contained in the notes for that bed number. However, it was not appreciated until later that a different patient was now occupying Bed 2 and that the request should have applied to the patient in Bed 3.

Circumstances leading to the detection of WBIT

In the majority of cases, the error was detected since there was a discrepancy between the groups of the current sample compared with the historical group.
In other circumstances:

- The clinical area identified that the incorrect patient had been bled (23 cases).
- The difference in identity was appreciated through unexpected changes in the results of other tests (10 cases):
  - Sequential full blood counts (FBCs) revealed unaccountable differences in red cell indices, white cell or platelet counts.
  - The Hb quoted on the request form for crossmatching did not match the known result for that patient.
- The error was appreciated when the laboratory telephoned the ward (7 cases):
  - Blood was available for a patient who had no prescription for blood while the ward was expecting blood to be available for a second patient.
  - Requesting a repeat sample from a patient for whom a crossmatch was not required.
  - Requesting a repeat sample because of an inadequately labelled sample.
  - To inform that there would be a delay in obtaining blood because of an unexpected antibody.
  - The laboratory could not find a patient on the theatre schedule with the name and clinical details provided on the request form.
  - The laboratory had not received a sample from the patient for whom an urgent crossmatch had been requested.
- The error was appreciated when the ward telephoned the laboratory (2 cases):
  - because the ward could not find any record of the FBC on the computer
  - to enquire whether the blood was available for the patient.
- Two samples arriving to the laboratory within a short space of time with the same identifiers but having different blood groups (patients in adjacent beds both labelled with one patient's details) or 2 samples with different patient identifiers but having identical haematological parameters (same patient has been bled twice).
- Maternal and neonatal samples had been transposed.

Request errors *n* = 44

Table 53
Categories of request errors

Category	No. of cases
Special requirements not requested	25
Request for incorrect patient	15
Request based on erroneous FBC	2
Inappropriate request for clinical situation	2
Total	**44**

The most common error was the omission of the request for specialist requirements, which were picked up by a variety of means, as shown in Table 54.

Table 54
Mode of detection that special requirements had not been requested *n* =25

Mode of detection	No. of cases
Contact between laboratories on patient transfer	1
Patient in possession of card indicating requirement for irradiated components	3
Patient in possession of antibody card	1
In laboratory, based on the clinical details provided	7
At the bedside pre-administration check	13
Total	**25**

Case 3

Patient's persistence in showing his antibody card avoids a transfusion of non-phenotyped units

A patient was in possession of an antibody card, which he showed to the phlebotomist. However, this information was not transmitted to the laboratory, the antibody screen was negative and non-phenotyped red cells were issued. The patient again presented his card to the nurse at the time of the bedside pre-administration check, following which antigen negative units were issued.

Requests for the incorrect patient *n* = 15

These were detected either in the laboratory when a verbal request was made to convert a G&S into a crossmatch and no sample was available, or at the bedside when units arrived and there was no prescription or indication that blood was required.

Anti-D Ig was requested for 5 incorrect patients, several of whom were RhD positive and 1 of whom was a male. These inconsistencies were not noted in the laboratory.

Inappropriate request for clinical situation *n* = 2

- Blood was requested for a patient when the doctor was unaware that the transfusion had taken place the previous evening.
- A neonate was prescribed 1 unit of red cells rather than a calculated volume.

Laboratory procedural or testing errors *n* = 119

Table 55
Categories of laboratory procedural or testing errors

Category	No. of errors
Sample booked in under incorrect record	9
Incorrect patient identifiers entered onto LIMS	27
Incorrect patient mergers on LIMS	2
Barcode reader errors	5
Manual grouping errors	9
Incorrect sample used for grouping	2
Incorrect sample used for crossmatching	4
Invalid sample used in crossmatching for a frequently transfused patient	9
Incomplete testing prior to issue	7
Inappropriate editing of results from analyser	4
Component mislabelled	34
Expired antibody identification panel in use	4
Other	3
Total	**119**

Sample booked in under incorrect record *n* = 9

Three of these errors were noted on testing a repeat sample, 3 during a 'final check'; the means of detecting the final 3 were not stated.

Incorrect patient identifiers entered onto LIMS *n* = 27

Fifteen errors were detected at the bedside, 1 at collection, 8 during testing or authorisation in the laboratory and in 3 cases were not stated.

Incorrect patient mergers on LIMS *n* = 2

Both of these errors were detected on testing a second sample.

Barcode reader errors *n* = 5

In 2 instances the ABO group was read incorrectly, in 2 the RhD group was read incorrectly and in 1 the expiry date was read incorrectly. All were detected at the bedside.

Manual grouping errors *n* = 9

These consisted of 5 transcription errors and 4 errors of interpretation. In 1 case an incorrect group was reported and in a second case the incorrect group of red cells was issued but later recalled. Two errors were noted by a second BMS checking the entries into LIMS, 2 at authorisation, 2 on testing the next sample from the patient and in the remaining 3 the means of detection were not stated.

Incorrect sample used for grouping *n* = 2

There were 2 cases, both of which were due to transposing the barcode labels allocated to adjacent samples in a rack.

Case 4

Barcodes allocated to adjacent samples transposed

The laboratory barcodes allocated to the adjacent samples of Patient A and Patient B were transposed. Patient A had no previous transfusion history, grouped as B positive and 2 units of red cells were issued. Patient B had historically grouped as B positive but on this occasion grouped as O positive. The red cells issued to Patient A were recalled.

Incorrect sample used for crossmatching *n* = 4

These cases were due to selecting the incorrect sample when converting a group and screen to a crossmatch. In 2 instances the errors were noted by the BMS removing the samples from the analyser and in the remaining 2 the errors were noted at authorisation.

Invalid sample used for crossmatching in a frequently transfused patient *n* = 9

Two of these errors were noted at crossmatching, 1 at issue, 5 during restocking and in 1 the means of detection was not stated.

Incomplete testing prior to issue *n* = 7

These errors were detected at authorisation or at a later stage in the process.

- Failure in a non-urgent situation to perform an antibody identification panel on patients with positive antibody screens with the intent to issue crossmatch compatible units (2 cases).
- Failure to perform a panel on patients with known antibodies (3 cases).
- To electronically issue red cells on samples with unexpected reactions with A1 or B cells on grouping and no further investigation (2 cases).

Inappropriate editing of results from analyser *n* = 4

- Weak positive antibody screens were edited to negative, in 1 case when the patient had a history of antibodies (error detected at authorisation) and in the second when a repeat sample 2 days later confirmed the presence of anti-K.
- Uninterpretable D groups edited to positive when on subsequent testing confirmed to be D negative.

Labelling errors *n* = 34

In 11 cases these errors were detected at collection, in 13 at the bedside and in 2 instances in the laboratory. In the remainder, the means of detection is unknown.

- Eight instances of platelets being labelled with another patient's ID, including 2 where the labels of 2 patients had been transposed.
- Twenty instances of labels being transposed between the units of red cells crossmatched for the same patient.
- Three instances where labels had been placed on units of red cells crossmatched for another patient, in 2 instances detected in the laboratory when the BMS found units he had crossmatched already in the issue fridge labelled for another patient, and in 1 case detected at the bedside.
- Three instances of FFP being labelled incorrectly, in 2 instances when the labels had been transposed between the units of FFP allocated to the same patient and in the third when the units had been labelled for another patient.

Expired antibody identification panel in use *n* = 4

In 1 case, the panel was found in the reagent fridge the following day and in 3 the errors were detected on entering the results onto LIMS.

Laboratory component selection errors *n* = 100

Table 56
Categories of laboratory component selection errors

Category	No. of cases
Special requirements or specification not met	65
Incorrect component selected	10
Component selected for a non-urgent transfusion with a reservation period beyond the expiry date	19
Anti-D Ig issued for an RhD positive female	6
Total	**100**

Special requirements or specification not met by laboratory *n* = 65

Errors made were either due to a failure to take heed of the information provided on the request form or computer flags, or, in the case of the provision of 'flying squad' and paediatric components, a lack of knowledge and failure to follow local SOP. Fifty-five of these were detected at the bedside, 6 when the component was collected from the issue fridge and 4 when recalled by the laboratory.

Table 57
Failure to issue components with special requirements or specification

Special requirement or specification	No. of cases
CMV negative	11
Irradiated	22
CMV negative and irradiated	11
HLA typed	3
Red cell phenotyped	8
Incorrect specification selected for 'flying squad'	6
Apheresis platelets	1
MB-FFP	1
Platelets in PSM	1
Washed red cells	1
Total	**65**

Wrong component selected *n* = 10

- 3 cases where an incorrect component was selected in an emergency on the basis of a verbal request (FFP instead of cryo or red cells).
- 2 cases where an incorrect dose of anti-D Ig was issued at delivery.
- 4 cases where computer flags were ignored with respect to group changes following SCT.
- 1 case when RhD positive platelets were issued to an RhD negative female, overriding the warnings.

Expired component selected *n* = 19

There were 19 cases where units were selected for crossmatch and reserved beyond the expiry date. These errors were picked up either at the bedside or during routine fridge clearance.

Collection errors *n* = 49

These were consistently detected at the pre-administration bedside check, although in several instances the units had been signed as correct when received into the clinical area. However, in 8/49 instances the unit had already been 'spiked', i.e. attached to a giving set prior to the pre-administration bedside check being conducted and the error being recognised.

The sources of errors were, when known, as follows:

- Porter not given a collection slip but only a verbal request for collection (3 cases).
- Inaccuracies on the collection slip (6 cases):
  - Given the incorrect collection slip.
  - Incorrect addressograph placed upon slip (2 cases).
  - Patient details otherwise incorrect (3 cases).
- The collection slip contained all the necessary patient identifiers but the staff member collecting the unit relied on family name alone to identify units, when units for 2 patients with the same surname were in the issue fridge (10 cases).
- Ignored warnings on removing incorrect unit from electronically controlled satellite fridge (6 cases).
- Collected the incorrect component (1 case), i.e. cryoprecipitate instead of platelets.
- Collected crossmatched rather than emergency O RhD negative from the issue fridge.

Case 5

Warnings ignored of blood being available in the issue fridge for 2 patients with the same surname

A porter went to collect blood without a blood collection slip and selected blood for an incorrect patient with the same surname. Stickers were in place on the units of blood and in the ledger to alert staff that blood was in the fridge for more than 1 patient with the same surname.

Case 6

Surgeon 'bucks' the protocol for collecting blood in an emergency

In an emergency, a porter had arrived at the hospital transfusion laboratory and was waiting for the BMS to come off the phone in order to collect the red cells. In the meantime a surgeon, somewhat frustrated by delays, collected them 'as he was passing blood bank', without signing the register.

Case 7

Over-riding an electronically controlled fridge

A unit of blood was taken from an electronically controlled fridge for a patient in theatre using the emergency access button, rather than using a staff ID barcode and entering the patient's details. The unit was 'spiked' before it was appreciated that the incorrect unit had been removed.

SAEs related to management of the cold chain *n* = 97

Table 58
Categories of SAEs related to management of the cold chain

SAE	No. of cases
Failure to follow procedure for transfer of units with the patient	13
Units kept in transport container for longer than the recommended period, including 3 cases where units were delivered to the incorrect location	33 (includes 4 near misses when the event was noted at time of transfusion)
Incorrect packaging of transport containers	2
Red cells stored in a non-designated refrigerator	7
Red cells stored in a freezer	2
Red cells temporarily placed in a bucket containing ice in theatre	1
Platelets stored in a fridge	4 (includes 1 case where BMS put platelets into the fridge)
Red cells placed in a satellite fridge known to be malfunctioning (alarming or awaiting engineer)	2
Satellite fridge alarms unheeded or where local staff unaware of correct procedure	7
Issue fridge alarms unheeded/muted	3
Satellite fridge failures	2
Attempts to return units that had been out of a temperature-controlled environment for more than 30 minutes to stock	11
Incomplete audit trails despite electronic blood tracking	10
Total	**97**

Case 8

BMS ignores hospital transfusion laboratory fridge alarm

During on-call, the hospital transfusion laboratory fridge alarmed as the door was left open. The BMS turned off the alarm without any investigation and the open fridge was detected the following morning by another BMS: 58 units of red cells were wasted.

Case 9

Lack of training for clinical staff cleaning satellite fridge

A new member of staff was cleaning the theatre fridge, and left the blood in the fridge instead of transferring it to a validated box. The fridge temperature increased to 7.5 °C and 16 units of blood were wasted.

Other clinical adverse events *n* = 9

- Incorrect transcription of blood group onto antenatal care pathway (4 cases).
- Failure of switchboard to raise the major haemorrhage alert.
- Failure to respond to request for a second sample on patients with antibodies, resulting in delays in the supply of red cells at the time of surgery (3 cases).
- Red cell unit spiked and then decision made that the patient was not fit for transfusion.

Case 10

Failure to assess patient before final administration check and lack of knowledge of correct blood-handling procedures

A unit of blood was left in a satellite fridge after being spiked with a giving set since a decision was taken that the patient was unfit for the transfusion at the time of the pre-administration bedside check. The transfusion laboratory received a phone call at 10.00 hours the following day requesting advice as to whether the unit was still safe to transfuse.

Blood Service adverse events *n* = 6

- No date on Radsure label.
- CMV negative platelets not labelled as such.
- Red cells issued in a container without ports.
- Incorrect red cell phenotype delivered.
- Crossmatch line not heat-sealed at the base.
- Error in reporting anti-D quantification.

COMMENTARY

While many of the learning points from this analysis have already been made in the main chapters of this report, several aspects merit mention here.

Firstly, with respect to sample labelling, the highest proportion of errors have been made by doctors who are not, under routine circumstances, expected to undertake this task. While all FY1 doctors must be assessed for venesection, it would appear that not all have been trained and competency assessed for this task with the rigor required by NPSA SPN 14.[1]

There were a total of 9 instances where the nurses had 'spiked' the blood before either starting the final administration check or ensuring that it was appropriate to transfuse the patient at that given time. This practice is wasteful of blood and contravenes the process of administering blood as documented in the BCSH guideline on the administration of blood components.[2]

It is also apparent that there is considerable blood wasted when it is transferred with the patient and is not packaged in accordance with validated policies to ensure component quality and safety. This practice should be rare and only considered when the patient is actively bleeding and is being escorted by a medical escort to a specialist unit.

Finally, there is evidence that clinical staff are not aware of, or disregard, the correct storage conditions for blood components and are not familiar with the procedures to be followed in the event of satellite fridge alarms.

Recommendations

- All Trusts must ensure that medical staff are trained and competency assessed for taking blood samples in accordance with the requirements of NPSA SPN 14.[1]

  Action: Deaneries, clinical risk managers, HTTs

- Education for staff involved in the transfusion process should include knowledge of the correct storage conditions for all blood components.

  Action: HTTs

- Each Trust should possess a policy and procedure for the transfer of blood components with a patient which reflects the guidance given by the NBTC and the NHSBT Appropriate Use of Blood Group.[3]

  Action: HTCs

22. Donor Adverse Event Reporting

Definition

A donor adverse event is a reaction affecting a donor linked to planned or actual donation, occurring shortly before, during or after donation. These reactions have no direct implication for the blood product or patient recipient.

Donor adverse events of donation (DAEDs) have long been recognised as occurring by UK Blood Services, and are recorded by the individual services. It is only in the last 2 years that the number of these events has been appreciated and the effects on the donors investigated in any detail.

The blood supply depends entirely on the daily commitment of volunteers, who ostensibly gain little personal benefit from blood donation but are exposed to potential risk of discomfort, complications and, in rare cases, injury resulting from the collection procedure. About 2–6% of all presenting donors experience an adverse event, most of which are classified as minor or moderate reactions that resolve promptly but are still unpleasant for the donor. SAEs occur infrequently.

DAEDs fall into two main categories:

- Events related to the venepuncture itself, producing local symptoms and generalised events.
- Events related to apheresis.

In 2008 the ISBT European (now International) Haemovigilance Network suggested a standardised international categorisation for these events (see Table 59).

Table 59
Standardised international categorisation for haemovigilance events

<table>
<tr><td rowspan="8">Local symptoms</td><td colspan="2" rowspan="3">Blood outside vessels</td><td>Haematoma</td></tr>
<tr><td>Arterial puncture</td></tr>
<tr><td>Delayed bleeding</td></tr>
<tr><td rowspan="3">Pain</td><td rowspan="2">Specified as</td><td>Nerve irritation</td></tr>
<tr><td>Nerve injury</td></tr>
<tr><td>Tendon injury</td></tr>
<tr><td>or not specified</td><td>Painful arm</td></tr>
<tr><td colspan="2" rowspan="2">Others</td><td>Thrombophlebitis</td></tr>
<tr><td>Allergy (local)</td></tr>
<tr><td rowspan="4">Generalised symptoms</td><td colspan="2" rowspan="4">Vasovagal reaction</td><td>Immediate</td></tr>
<tr><td>Immediate with injury</td></tr>
<tr><td>Delayed</td></tr>
<tr><td>Delayed with injury</td></tr>
<tr><td colspan="3" rowspan="4">Related to apheresis</td><td>Citrate reaction</td></tr>
<tr><td>Haemolysis</td></tr>
<tr><td>Generalised allergic reaction</td></tr>
<tr><td>Air embolism</td></tr>
<tr><td colspan="4">Other</td></tr>
</table>

They went on to suggest grading these events as minor or moderate. The UK Blood Services are hoping to submit numerical data for adverse events mapped to these categories to SHOT from 2011.

The Haemovigilance Network define severe events as those that resulted in:

Hospitalisation:	if it was attributable to the event
Intervention:	to prevent permanent damage or impairment of a body function or to prevent death
Symptoms:	causing significant disability or incapacity persisting for more than a year after the donation
Death:	if it was possibly, probably or definitely related to the donation.

Table 60
Definitions for serious adverse events of donation (SAEDs) agreed by UK Blood Services

SAED category
Death within 7 days of donation
Hospital admission within 24 hours of donation
Injury resulting in a fracture within 24 hours
Road traffic collision within 24 hours of donation
Acute coronary syndrome (ACS) diagnosed within 24 hours of donation
Problems relating to needle insertion persisting for more than a year
Anaphylaxis, haemolysis or air embolism (component donation, CD)

These are in line with the ISBT European (now International) Haemovigilance Network guidance, but more specific. In line with the guidance from the network all SAEDs will be investigated and the strength of the relationship between the donation and the event will be determined as:

Definite or certain:	when there is conclusive evidence beyond reasonable doubt for the relationship
Probable or likely:	when the evidence is clearly in favour of a relationship
Possible:	when the evidence is indeterminate for attributing the complication to the donation or an alternative cause
Unlikely or doubtful:	when the evidence is clearly in favour of attributing the complication to other causes
Excluded:	when there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.

Only cases with imputability of possible, probable or definite will be reported to SHOT.

Sue Barnes FCEM

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24. Glossary

A&E	Accident and emergency
AAGBI	Association of Anaesthetists Great Britain and Ireland
ACD	Acid citrate dextrose
ACE	Angiotensin converting enzyme
ACS	Acute coronary syndrome
AHTR	Acute haemolytic transfusion reaction
ALI	Acute lung injury
ALL	Acute lymphoblastic leukaemia
AML	Acute myeloid leukaemia
ANH	Acute normovolaemic haemodilution
ARDS	Acute respiratory distress syndrome
ATG	Anti-thymocyte globulin
ATR	Acute transfusion reaction
ATRA	All-trans retinoic acid
BBTS	British Blood Transfusion Society
BCSH	British Committee for Standards in Haematology
BIPAP	Bilevel positive airway pressure
BMS	Biomedical scientist
BMT	Bone marrow transplant
BP	Blood pressure
BPM	Beats per minute
BSQR	Blood Safety and Quality Regulations
CAPA	Corrective and preventative actions
CCF	Congestive cardiac failure
CD	Component donation
CEO	Chief executive officer
CLL	Chronic lymphocytic leukaemia
CML	Chronic myeloid leukaemia
CMO	Chief medical officer
CMV	Cytomegalovirus
CPA	Clinical pathology accreditation
CPAP	Continuous positive airway pressure
CPR	Cardiopulmonary resuscitation
CRF	Chronic renal failure
Cryo	Cryoprecipitate
CTS	Controlled temperature storage
CVP	Central venous pressure
CXR	Chest X-ray
DAT	Direct antiglobulin test
DAEDS	Donor adverse events of donation
DH	Department of Health
DHTR	Delayed haemolytic transfusion reaction
DNA	Deoxyribose nucleic acid
DOB	Date of birth
DSTR	Delayed serological transfusion reaction
ECG	Electrocardiogram
ECHO	Echocardiogram
EI	Electronic issue
ET	Exchange transfusion
FBC	Full blood count
FFP	Fresh frozen plasma
FMH	Fetomaternal haemorrhage
FNHTR	Febrile non-haemolytic transfusion reaction
FY	Foundation year
G&S	Group and save
GI	Gastrointestinal
GCS	Glasgow Coma Scale/Score
GMC	General Medical Council
GP	General practitioner
Gynae	Gynaecology
HAV	Hepatitis A virus
Hb	Haemoglobin
HBV	Hepatitis B virus
HCV	Hepatitis C virus
HDU	High-dependency unit
HEV	Hepatitis E virus
HIV	Human immunodeficiency virus
HLA	Human leucocyte antigen
HNA	Human neutrophil antigen
HPA	Human platelet antigen **or** Health Protection Agency
HPLC	High-performance liquid chromatography
HSC	Health service circular
HSE	Handling and storage errors
HTC	Hospital transfusion committee
HTLV	Human T-cell lymphotropic virus
HTR	Haemolytic transfusion reactions
HTT	Hospital transfusion team
I&U	Inappropriate, unnecessary and under/delayed transfusion
IAT	Indirect antiglobulin test
IBCT	Incorrect blood component transfused
IBGRL	International Blood Group Reference Laboratory
IBMS	Institute of Biomedical Science
ICS	Intraoperative cell salvage
ID	Identification
Ig	Immunoglobulin
iu	International units
IHD	Ischaemic heart disease
IHN	International Haemovigilance Network
IM	Intramuscular
INR	International Normalised Ratio
ISBT	International Society of Blood Transfusion
IT	Information technology
ITU	Intensive therapy unit
IUT	Intrauterine transfusion
IV	Intravenous
JVP	Jugular venous pressure
LDF	Leucocyte depletion filter
kPa	KiloPascal

LDH	Lactate dehydrogenase enzyme
LIMS	Laboratory information management system
LVF	Left ventricular failure
MAU	Medical assessment unit
MB-FFP	Methylene-blue fresh frozen plasma
MCT	Mast cell tryptase
MHRA	Medicines and Healthcare products Regulatory Agency
MLA	Medical laboratory assistant
MOF	Multiorgan failure
NAITP	Neonatal alloimmune thrombocytopenia
NBTC	National Blood Transfusion Committee
NCA	National Comparative Audit
NHS	National Health Service
NHSBT	NHS Blood and Transplant
NIBTS	Northern Ireland Blood Transfusion Service
NNU	Neonatal unit
NPSA	National Patient Safety Agency
NWIS	NHS Wales Informatics Service
OAS	Optimal additive solution
ODP	Operating department practitioner
O&G	Obstetrics and gynaecology
PAD	Preoperative autologous donation
PAS	Patient administration system
PCC	Prothrombin complex concentrate
PCS	Postoperative cell salvage
PE	Pulmonary embolism
PEA	Pulseless electrical activity
PEX	Plasma exchange
PICU	Paediatric intensive care unit
PMETB	Postgraduate Medical Education Board
POCT	Point of care testing
Pos	Positive
pO_2	Partial pressure of oxygen
PPH	Postpartum haemorrhage
PMETB	Postgraduate Medical Education Training Board
PSE	Potentially sensitising event
PTP	Post-transfusion purpura
PV	Per vaginam
RAADP	Routine antenatal anti-D prophylaxis
RBC	Red blood cells
RBCOA	Red blood cells in optimal additive solution
RBRP	Right blood right patient
RCI	Red cell immunohaemotology
RCP	Royal College of Physicians
RNA	Ribonucleic acid
RR	Respiratory rate
RTA	Road traffic accident
RTC	Regional transfusion committee
SABRE	Serious adverse blood reactions and events
SAE	Serious adverse event
SAEDs	Serious adverse events of donation
SCA	Sickle cell anaemia
SCT	Stem cell transplant
SCTAC	Scottish Clinical Transfusion Advisory Committee
SD	Solvent detergent
SD-FFP	Solvent detergent treated fresh frozen plasma
SG	Steering group
SNBTS	Scottish National Blood Transfusion Service
SOB	Short of breath
SOP	Standard operating procedure
SPN	Safer practice notice
SpR	Specialist registrar
SRNM	Special requirements not met
TACO	Transfusion-associated circulatory overload
TAD	Transfusion-associated dyspnoea
TA-GvHD	Transfusion-associated graft versus host disease
THR	Total hip replacement
TKR	Total knee replacement
TPH	Transplacental haemorrhage
TRALI	Transfusion-related acute lung injury
TTI	Transfusion-transmitted infection
TTP	Thrombotic thrombocytopenic purpura
Tx	Transfusion
UK NEQAS BTLP	UK National External Quality Assessment Scheme for Blood Transfusion Laboratory Practice
UKTLC	UK Transfusion Laboratory Collaborative
UKRC	UK Resuscitaion Council
vCJD	Variant Creutzfeld Jakob Disease
WBIT	Wrong blood in tube
WBS	Welsh Blood Service
WCC	White cell count
WEG	Working Expert Group

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